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JAN 25 2005
PATENT & TRADEMARK OFFICE

PATENT
Docket No. 57314US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s): PARTHASARATHY et al.) Group Art Unit: 1743
)
Serial No.: 10/027,222) Examiner: Dwayne K. Handy
Confirmation No.: 9052)
)
Filed: December 20, 2001)
)
For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES
 FROM BIOLOGICAL MIXTURES USING ANION EXCHANGE

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Appeal Brief is presented in support of the Notice of Appeal filed October 27, 2004, from the final rejection of claims 39-42, 44-45, 53-54, and 64-65 of the above-identified application under 37 C.F.R. §§1.113 and 1.191. This Appeal Brief is being submitted as set forth in 37 C.F.R. §41.37. Please charge Deposit Account No. 13-4895 the fee for filing this Brief under 37 C.F.R. §41.20(b)(2).

Real Party in Interest

The real party in interest of the above-identified patent application is the assignee, 3M Innovative Properties Company, as evidenced by the assignment recorded at Reel 13054, Frame 943.

Related Appeals and Interferences

There are no appeals or interferences known to Appellants' Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

Status of Claims

Claims 43, 46-52, and 55-63 having been canceled, the pending claims are claims 1-42, 44-45, 53-54, and 64-65, all of which are listed in the CLAIMS APPENDIX. The Examiner having withdrawn claims 1-38 from consideration, the claims currently under appeal are claims 39-42, 44-45, 53-54, and 64-65, all of which are rejected.

Claims 39-42, 44-45, and 54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53 and 56-61 of U.S. Patent Application Serial No. 10/417,609. Claims 39-42 and 54 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 50-53 of U.S. Patent Application Serial No. 10/272,226 in view of Nelson et al. (U.S. Patent No. 6,344,326). Appellants note that in the Final Office Action mailed July 27, 2004, the Examiner based the second rejection on U.S. Patent Application No. 10/272,226. However, the rejection in the Office Action mailed January 6, 2004 was based on U.S. Patent Application No. 10/027,226. In the event the rejection is maintained, clarification is again respectfully requested.

The provisional obviousness-type double patenting rejections of claims 39-42, 44-45, and 54 are not at issue in this appeal, as upon an indication of otherwise allowable subject matter and in the event this rejection is maintained, Appellants will provide an appropriate response. In the event that the provisional obviousness-type double patenting

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rejections are the only rejections remaining in the present application, the Examiner is respectfully requested to withdraw the provisional obviousness-type double patenting rejection and allow the present application to issue as a patent pursuant to M.P.E.P. §822.01.

Claims 1-38, which have been withdrawn from consideration by the Examiner, recite methods of using a device as recited, for example, in claim 39. Specifically, independent claims 1-2, 17-18, 20-21, and 36 recite language from independent claim 39. Upon an indication of claim 39 being allowable, Appellants respectfully request that the method claims (e.g., claims 1-38) also be examined and passed on to allowance pursuant to M.P.E.P. §821.04. *See, for example, In re Ochiai, 71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995)* and *In re Brouwer, 77 F.3d 422, 37 U.S.P.Q.2d (BNA) 1663 (Fed. Cir. 1996)*.

Status of Amendments

An Amendment and Response under 37 C.F.R § 1.116 was submitted, which the Examiner indicated would be entered for purposes of Appeal in the Advisory Action mailed October 25, 2004. No claims were amended in the Amendment and Response under 37 C.F.R §1.116.

Summary of Claimed Subject Matter

Independent claim 39 recites a device (e.g. reference numeral 110 in FIG. 2 and page 28, lines 1-20 of the present specification) including a plurality of process arrays (e.g. FIG. 2 and page 28, lines 20-30 of the present specification). Each process array includes a plurality of process chambers (e.g. reference numerals 150(a-c) in FIG. 2 and page 28, lines 3-9 of the present specification). Each process chambers defines a volume

for containing a biological sample mixture (e.g., page 8, lines 3-6 of the present specification). Further, at least one distribution channel (e.g., reference numerals 160 (a-c) and page 28, lines 5-6 of the present specification) connects the plurality of process chambers of the array. At least one of the process arrays includes a surface including an anion exchange material partially coated with a negatively charged polymer (e.g., page 13, lines 8-10 of the present specification). The device is operable to remove small negatively charged organic molecules from the biological sample mixture (e.g., page 7, line 31 of the present specification).

Independent claim 64 recites a device (e.g. reference numeral 110 in FIG. 2 and page 28, lines 1-20 of the present specification) including a plurality of process arrays (e.g. FIG. 2 and page 28, lines 20-30 of the present specification). Each process array includes a plurality of process chambers (e.g. reference numerals 150(a-c) in FIG. 2 and page 28, lines 3-9 of the present specification). Each process chambers defines a volume for containing a biological sample mixture (e.g., page 8, lines 3-6 of the present specification). Further, at least one distribution channel (e.g., reference numerals 160 (a-c) and page 28, lines 5-6 of the present specification) connects the plurality of process chambers of the array. At least one of the process arrays includes a surface including quaternary ammonium ions partially coated with a negatively charged polyelectrolyte (e.g., page 13, lines 8-10 of the present specification). The device is operable to remove small negatively charged organic molecules from the biological sample mixture (e.g., page 7, line 31 of the present specification).

Independent claim 65 recites a device (e.g. reference numeral 110 in FIG. 2 and page 28, lines 1-20 of the present specification) including a plurality of process arrays (e.g. FIG. 2 and page 28, lines 20-30 of the present specification). Each process array includes a plurality of process chambers (e.g. reference numerals 150(a-c) in FIG. 2 and

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page 28, lines 3-9 of the present specification). Each process chambers defines a volume for containing a biological sample mixture including a nucleic acid amplification reaction mixture (e.g., page 8, lines 3-6 of the present specification). Further, at least one distribution channel (e.g., reference numerals 160 (a-c) and page 28, lines 5-6 of the present specification) connects the plurality of process chambers of the array. At least one of the process arrays includes a surface including quaternary ammonium ions partially coated with a negatively charged polyelectrolyte (e.g., page 13, lines 8-10 of the present specification). The device is operable to remove small negatively charged organic molecules from the biological sample mixture (e.g., page 7, line 31 of the present specification).

Grounds of Rejection to be Reviewed on Appeal

- I. Claims 39-41, 44-45, 53-54, and 64-65 stand rejected under 35 U.S.C. §103(a) as being obvious over Nelson et al. (U.S. Patent No. 6,344,326) in view of Gjerde et al. (U.S. Patent No. 6,265,168).
- II. Claim 42 stands rejected under 35 U.S.C. §103(a) as being obvious over Nelson et al. (U.S. Pat. No. 6,344,326) in view of Gjerde et al. (U.S. Pat. No. 6,265,168) as applied above, and further in view of Mian et al. (U.S. Pat. No. 6,319,469).

Argument

- I. **Claims 39-41, 44-45, 53-54, and 64-65 stand rejected under 35 U.S.C. §103(a) as being obvious over Nelson et al. (U.S. Patent No. 6,344,326) in view of Gjerde et al. (U.S. Patent No. 6,265,168). Appellants respectfully traverse the rejection, and request review and reversal by the Board.**

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A. NEITHER NELSON ET AL. NOR GJERDE ET AL. TEACH OR SUGGEST THE USE OF A NEGATIVELY CHARGED MATERIAL.

“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974), M.P.E.P. §2143.03. Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness.

The Amendment and Response submitted by Appellants on 3 October 2003 included remarks (e.g., pages 19-21), which Appellants hereby incorporate by reference in the present response, arguing that both Nelson et al. and Gjerde et al. lack, among other things, a disclosure or suggestion of a device that includes a plurality of process arrays wherein at least one of the process arrays comprises a *surface* comprising ***an anion exchange material partially coated with a negatively charged polymer*** (e.g., present independent claim 39).

Specifically, the Examiner asserted that an anion exchange material partially coated ***with a negatively charged polymer*** is disclosed at column 30, lines 31-33 of Gjerde et al. Appellants earnestly disagree.

Gjerde et al., recite the following:

The materials used currently in the MIPC column matrix of this invention, as well as other materials suitable for MIPC (as one example, larger polymeric particle sizes of nonporous reverse-phase materials), are known to have an exceptionally high capacity and selectivity for long-chain nucleic acids. By applying a suitable pairing ion, and then changing nothing other than the acetonitrile concentration (or any other suitable solvent, such as an alcohol), the quantitative adsorption/desorption of varying lengths of short- and long-chain nucleic acids are essentially turned on and off. Furthermore, since the matrix is made of a nonporous

polymeric material, there is no opportunity for interlopers (dNTPs, primers, primer dimers, non-specific amplification products) to get trapped and become problematic downstream. In essence, the matrix materials we possess (nonporous polystyrene-divinylbenzene, either unalkylated or alkylated) are perfectly suited to the purification of PCR products prior to the most demanding molecular biology applications. Also suitable are nonporous polymeric or modified silica materials which has been manufactured or purified in a manner which produces surfaces which are free of contamination. These can be in the form of beads, monoliths, channels, capillary or planar surfaces. *The polymeric surfaces can be provided by non-alkylated and alkylated materials including polystyrene, divinylbenzene, hydroxyethylmethacrylate, and other nonionic polymers.*

(column 30, lines 5-30). Thus, Appellants respectfully submit that Gjerde et al. clearly disclose the use of *nonionic polymers*.

Further, Gjerde et al., at column 30, lines 31-33, explicitly state that "[p]olymers having a negative charge may also be used provided the charged groups are *protonated to produce a neutral surface, i.e., carboxylic acid*" (emphasis added). In other words, Gjerde et al. are disclosing that polymers that initially have a negative charge (e.g., negatively charged carboxylate groups, i.e., $-CO_2^-$ groups) may be used provided that the charged groups are protonated to produce a neutral surface (e.g., uncharged carboxylic acid groups, i.e., $-CO_2H$ groups). In short, the recitation at column 30, lines 31-33 of Gjerde et al. reinforces the use of *uncharged (e.g., nonionic) polymers* that can include, for example, uncharged carboxylic acid groups.

B. LANGUAGE MUST BE GIVEN PLAIN AND ORDINARY MEANING.

"Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say." M.P.E.P. §2111.01.

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Gjerde et al. explicitly state that "[p]olymers having a negative charge may also be used provided the charged groups are *protonated to produce a neutral surface, i.e., carboxylic acid*" (column 30, lines 32-33; emphasis added). Appellants respectfully note that Gjerde et al. do not recite that *some* of the charged groups are protonated. As such, Appellants respectfully submit that Gjerde et al. teach the use of a formerly charged surface, not a charged surface.

Nonetheless, the Examiner stated that "an anion exchange material that has negative polymeric groups in which some of the groups are protonated still meets the limitation of the claim since the anionic exchange material is still a surface that is still partially has a negatively charged polymer" (e.g., page 2, lines 8-10 of the Advisory Action mailed 25 October 2004). Appellants earnestly disagree.

Appellants respectfully submit that the Examiner's characterization of Gjerde et al. as teaching an anion exchange material "in which some of the groups are protonated" is not supported by the plain and ordinary meaning of the language used by Gjerde et al. (e.g., "**provided the charged groups are protonated to produce a neutral surface, i.e., carboxylic acid.**" Column 30, lines 32-33; emphasis added).

C. *EVIDENTIARY SUPPORT FOR SCIENTIFIC THEORY MUST BE PROVIDED.*

"The rationale to support a rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle. *In re Soli*, 317 F.2d 941, 137 U.S.P.Q. (BNA) 797 (CCPA 1963). However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided." *In re Grose*, 592 F.2d 1161, 201 U.S.P.Q. (BNA) 57 (CCPA 1979), M.P.E.P. §2144.02.

The Examiner stated that "[a]pplicants appear to be treating the teaching of protonation from Gjerde as an irreversible change in the exchange material that totally

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eliminates the presence of the anionic polymer groups. This is not the case with ionic exchange material" (e.g., page 2, lines 4-6 of the Advisory Action mailed 25 October 2004). Appellants respectfully disagree with the Examiner's assertion.

First, to the extent that the Examiner is basing the rejection on the theory of "reversibility" (i.e., a scientific theory), Appellants respectfully submit that the Examiner failed to provide any evidentiary support for the theory being presented, as is required under the rules (e.g., M.P.E.P. §2144.02).

Second, Appellants respectfully submit that issue of reversible protonation is not relevant to the present rejection. As noted herein above, Gjerde et al. teach the use of uncharged groups (e.g., "**provided the charged groups are protonated to produce a neutral surface, i.e., carboxylic acid**"). Gjerde et al. provide no suggestion for any reversibility of the protonation.

Based on the remarks presented herein above, Appellants respectfully submit that the Examiner has failed to present a *prima facie* case of unpatentability of claims 39-41, 44-45, 53-54, and 64-65 over Nelson et al. in view of Gjerde et al.

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II. Claim 42 stands rejected under 35 U.S.C. §103(a) as being obvious over Nelson et al. (U.S. Pat. No. 6,344,326) in view of Gjerde et al. (U.S. Pat. No. 6,265,168) as applied above, and further in view of Mian et al. (U.S. Pat. No. 6,319,469).

Appellants respectfully traverse the rejection, and request review and reversal by the Board.

Claim 42 depends from independent claim 39. Appellants respectfully submit that Mian et al. provide nothing to correct the deficiencies of Nelson et al. in view of Gjerde et al. Thus, Appellants respectfully submit that claim 42 is patentable for at least the reasons presented herein above for the patentability of independent claim 39, in addition to the subject matter recited therein.

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Conclusion

For at least the reasons presented herein above, Appellants respectfully submit that the Examiner has failed to present a *prima facie* case of unpatentability of claims 39-42, 44-45, 53-54, and 64-65. Review and reversal of the rejection of claims 39-42, 44-45, 53-54, and 64-65 is respectfully requested.

Respectfully submitted,

PARTHASARATHY et al.

By

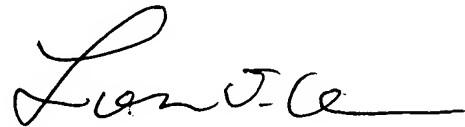
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By: 

Name: Rachel Gagliardi-Gibson

CLAIMS APPENDIX
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1. **(Withdrawn)** A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:

 providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

 a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

 at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising an anion exchange material partially coated with a negatively charged polymer;

 providing a biological sample mixture comprising small negatively charged organic molecules having a molecular weight of less than about 6,000; wherein the biological sample mixture is selected from the group consisting of a nucleic acid amplification reaction mixture and a nucleic acid labeling reaction mixture; and

 contacting the biological sample mixture with the surface comprising the anion exchange material to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture.

2. **(Withdrawn)** A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:

 providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

 a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

 at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising an anion exchange material partially coated with a negatively charged polymer;
 providing a biological sample mixture; and

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contacting the biological sample mixture with the surface comprising an anion exchange material partially coated with a negatively charged polymer to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture.

3. **(Withdrawn)** The method of claim 2 wherein the negatively charged polymer is a polyelectrolyte.
4. **(Withdrawn)** The method of claim 3 wherein the negatively charged polyelectrolyte is selected from the group consisting of a polystyrene sulfonic acid, polyvinyl phosphonic acid, polyvinyl boric acid, polyvinyl sulfonic acid, polyvinyl sulfuric acid, polystyrene phosphonic acid, polyacrylic acid, polymethacrylic acid, lignosulfonate, carrageenan, heparin, chondritin sulfate, salts thereof, and mixtures thereof.
5. **(Withdrawn)** The method of claim 2 wherein the anion exchange material comprises quaternized nitrogen.
6. **(Withdrawn)** The method of claim 2 wherein the biological sample mixture is a nucleic acid sequencing reaction mixture.
7. **(Withdrawn)** The method of claim 6 wherein the small negatively charged organic molecules are selected from the group consisting of dye-labeled terminators, primers, degraded dye molecules, deoxynucleotide triphosphates, and mixtures thereof.
8. **(Withdrawn)** The method of claim 7 wherein the small negatively charged organic molecules comprise dye-labeled terminators.

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9. **(Withdrawn)** The method of claim 8 wherein the dye-labeled terminators are selected from the group consisting of dideoxynucleotide triphosphates, dideoxynucleotide diphosphates, dideoxynucleotide monophosphates, dideoxynucleosides, and combinations thereof.

10. **(Withdrawn)** The method of claim 8 wherein contacting the biological sample mixture with the surface comprising an anion exchange material partially coated with a negatively charged polymer is carried out under conditions effective to remove substantially all the dye-labeled terminators from the biological sample mixture.

11. **(Withdrawn)** The method of claim 2 wherein the biological sample mixture is a PCR reaction mixture.

12. **(Withdrawn)** The method of claim 11 wherein the small negatively charged organic molecules are selected from the group consisting of primers, degraded dye molecules, deoxynucleotide triphosphates, and mixtures thereof.

13. **(Withdrawn)** The method of claim 12 wherein contacting the biological sample mixture with the surface comprising an anion exchange material partially coated with a negatively charged polymer is carried out under conditions effective to remove substantially all the primers from the biological sample mixture.

14. **(Withdrawn)** The method of claim 2 wherein the small negatively charged organic molecules have a molecular weight of less than about 6,000.

15. **(Withdrawn)** The method of claim 2 wherein contacting the biological sample mixture with the surface comprising an anion exchange material partially coated with a negatively

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charged polymer comprises agitating while contacting.

16. **(Withdrawn)** The method of claim 2 wherein the device is a microfluidic device.

17. **(Withdrawn)** A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:

 providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

 a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

 at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising quaternary ammonium ions partially coated with a negatively charged polyelectrolyte;

 providing a biological sample mixture; and

 contacting the biological sample mixture with the surface comprising quaternary ammonium ions partially coated with a negatively charged polyelectrolyte to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture.

18. **(Withdrawn)** A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:

 providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

 a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

 at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising

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quaternary ammonium ions partially coated with a negatively charged polyelectrolyte; providing a biological sample mixture; and contacting the biological sample mixture with the surface comprising quaternary ammonium ions partially coated with a negatively charged polyelectrolyte to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture; wherein the biological sample mixture comprises a nucleic acid amplification reaction mixture.

19. (Withdrawn) The method of claim 18 wherein the device is a microfluidic device.

20. (Withdrawn) A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:

providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising an anion exchange material;

providing a biological sample mixture in the at least one process array, wherein the biological sample mixture comprises small negatively charged organic molecules having a molecular weight of less than about 6,000; and

transferring the biological sample mixture within the at least one process array, wherein the biological sample mixture and the surface comprising an anion exchange material remain in contact for a sufficient time to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture.

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21. **(Withdrawn)** A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:

providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising an anion exchange material partially coated with a negatively charged polymer;

providing a biological sample mixture in the at least one process array; and

transferring the biological sample mixture within the at least one process array, wherein the biological sample mixture and the surface comprising an anion exchange material partially coated with a negatively charged polymer remain in contact for a sufficient time to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture.

22. **(Withdrawn)** The method of claim 21 wherein the negatively charged polymer is a polyelectrolyte.

23. **(Withdrawn)** The method of claim 22 wherein the negatively charged polyelectrolyte is selected from the group consisting of a polystyrene sulfonic acid, polyvinyl phosphonic acid, polyvinyl boric acid, polyvinyl sulfonic acid, polyvinyl sulfuric acid, polystyrene phosphonic acid, polyacrylic acid, polymethacrylic acid, lignosulfonate, carrageenan, heparin, chondritin sulfate, salts thereof, and mixtures thereof.

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24. **(Withdrawn)** The method of claim 21 wherein the anion exchange material comprises quaternary ammonium ions.

25. **(Withdrawn)** The method of claim 21 wherein the biological sample mixture is a nucleic acid sequencing reaction mixture.

26. **(Withdrawn)** The method of claim 25 wherein the small negatively charged organic molecules are selected from the group consisting of dye-labeled terminators, primers, degraded dye molecules, deoxynucleotide triphosphates, and mixtures thereof.

27. **(Withdrawn)** The method of claim 26 wherein the small negatively charged organic molecules comprise dye-labeled terminators.

28. **(Withdrawn)** The method of claim 27 wherein the dye-labeled terminators are selected from the group consisting of dideoxynucleotide triphosphates, dideoxynucleotide diphosphates, dideoxynucleotide monophosphates, dideoxynucleosides, and combinations thereof.

29. **(Withdrawn)** The method of claim 27 wherein the biological sample mixture and the surface comprising an anion exchange material partially coated with a negatively charged polymer are contacted under conditions effective to remove substantially all the dye-labeled terminators from the biological sample mixture.

30. **(Withdrawn)** The method of claim 21 wherein the biological sample mixture is a PCR reaction mixture.

31. **(Withdrawn)** The method of claim 30 wherein the small negatively charged organic

molecules are selected from the group consisting of primers, degraded dye molecules, deoxynucleotide triphosphates, and mixtures thereof.

32. **(Withdrawn)** The method of claim 31 wherein the biological sample mixture and the surface comprising an anion exchange material partially coated with a negatively charged polymer are contacted under conditions effective to remove substantially all the primers from the biological sample mixture.
33. **(Withdrawn)** The method of claim 21 wherein the small negatively charged organic molecules have a molecular weight of less than about 6,000.
34. **(Withdrawn)** The method of claim 21 wherein the biological sample mixture and the surface comprising an anion exchange material partially coated with a negatively charged polymer are agitated while in contact.
35. **(Withdrawn)** The method of claim 21 wherein the at least one process array comprises a loading chamber and at least one process chamber.
36. **(Withdrawn)** A method of removing small negatively charged organic molecules from a biological sample mixture, the method comprising:
 providing a device comprising a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:
 a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and
 at least one distribution channel connecting the plurality of process chambers of the array; wherein at least one of the process arrays comprises a surface comprising

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quaternary ammonium ions partially coated with a negatively charged polyelectrolyte; providing a biological sample mixture in the at least one process array; and

transferring the biological sample mixture within the at least one process array, wherein the biological sample mixture and the surface comprising quaternary ammonium ions partially coated with a negatively charged polyelectrolyte remain in contact for a sufficient time to remove at least a portion of the small negatively charged organic molecules from the biological sample mixture.

37. (Withdrawn) The method of claim 36 wherein the biological sample mixture comprises a nucleic acid amplification reaction mixture.

38. (Withdrawn) The method of claim 36 wherein the biological sample mixture and the surface comprising quaternary ammonium ions partially coated with a negatively charged polyelectrolyte are agitated while in contact.

39. (Rejected) A device comprising:

a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

at least one distribution channel connecting the plurality of process chambers of the array;

wherein at least one of the process arrays comprises a surface comprising an anion exchange material partially coated with a negatively charged polymer; and

wherein the device is operable to remove small negatively charged organic molecules from the biological sample mixture.

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For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING ANION EXCHANGE

40. **(Rejected)** The device of claim 39 further comprising a plurality of valves, wherein at least one of the valves is located along the at least one distribution channel.

41. **(Rejected)** The device of claim 39 wherein the plurality of process arrays comprises a plurality of independent process arrays.

42. **(Rejected)** The device of claim 39 wherein the plurality of process arrays are arranged radially on the device.

43. **(Canceled)**

44. **(Rejected)** The device of claim 39 wherein the negatively charged polymer is a polyelectrolyte.

45. **(Rejected)** The device of claim 39 wherein the anion exchange material, the negatively charged polymer, or both are pattern coated.

46-52. **(Canceled)**

53. **(Rejected)** The device of claim 44 wherein the negatively charged polyelectrolyte is selected from the group consisting of a polystyrene sulfonic acid, polyvinyl phosphonic acid, polyvinyl boric acid, polyvinyl sulfonic acid, polyvinyl sulfuric acid, polystyrene phosphonic acid, polyacrylic acid, polymethacrylic acid, lignosulfonate, carrageenan, heparin, chondritin sulfate, salts thereof, and mixtures thereof.

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54. **(Rejected)** The device of claim 39 wherein the anion exchange material comprises quaternized nitrogen.

55-63. **(Canceled)**

64. **(Rejected)** A device comprising:

a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture; and

at least one distribution channel connecting the plurality of process chambers of the array;

wherein at least one of the process arrays comprises a surface comprising quaternary ammonium ions partially coated with a negatively charged polyelectrolyte; and

wherein the device is operable to remove small negatively charged organic molecules from the biological sample mixture.

65. **(Rejected)** A device comprising:

a plurality of process arrays, wherein each process array of the plurality of process arrays comprises:

a plurality of process chambers, each of the process chambers defining a volume for containing a biological sample mixture comprising a nucleic acid amplification reaction mixture; and

at least one distribution channel connecting the plurality of process chambers of the array;

wherein at least one of the process arrays comprises a surface comprising quaternary

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ammonium ions partially coated with a negatively charged polyelectrolyte; and

wherein the device is operable to remove small negatively charged organic molecules from the biological sample mixture.

O I P E
JAN 25 2005
PATENT & TRADEMARK OFFICE

EVIDENCE APPENDIX
Serial No.: 10/027,222
Docket No.: 57314US002

1. Nelson et al., U.S. Patent No. 6,344,326 (first cited by the Examiner in the rejection under 35 U.S.C. §102(e) on page 6 of the Non-final Office Action mailed July 3, 2003).
2. Gjerde et al., U.S. Patent No. 6,265,168 (first cited by the Examiner in the rejection under 35 U.S.C. §103(a) on page 9 of the Non-final Office Action mailed July 3, 2003).
3. Mian et al., U.S. Patent No. 6,319,469 (first cited by the Examiner in the rejection under 35 U.S.C. §103(a) on page 5 of the Non-final Office Action mailed January 6, 2004).

Appendix C - CITED AUTHORITIES AND DOCUMENTS

Page C-1

Serial No.: 10/027,222

Confirmation No.: 9052

Filed: December 20, 2001

For: METHODS AND DEVICES FOR REMOVAL OF ORGANIC MOLECULES FROM BIOLOGICAL MIXTURES USING ANION EXCHANGE

1. M.P.E.P. §822.01 (Eighth Edition, May 2004 revision).
2. M.P.E.P. §821.04 (Eighth Edition, May 2004 revision).
3. *In re Ochiai*, 71 F.3d 1565, 37 U.S.P.Q.2d (BNA) 1127 (Fed. Cir. 1995).
4. *In re Brouwer*, 77 F.3d 422, 37 U.S.P.Q.2d (BNA) 1663 (Fed. Cir. 1996).
5. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. (BNA) 580 (CCPA 1974).
6. M.P.E.P. §2143.03 (Eighth Edition, May 2004 revision).
7. *In re Soli*, 317 F.2d 941, 137 U.S.P.Q. (BNA) 797 (CCPA 1963).
8. *In re Grose*, 592 F.2d 1161, 201 U.S.P.Q. (BNA) 57 (CCPA 1979).
9. M.P.E.P. §2144.02 (Eighth Edition, May 2004 revision).
10. M.P.E.P. §2111.01 (Eighth Edition, May 2004 revision).

See MPEP § 804.03 for conflicting subject matter, different inventors, common ownership.

See MPEP § 706.03(k) for rejection of one claim on another in the same application.

See MPEP § 706.03(w) and § 706.07(b) for *res judicata*.

See MPEP § 709.01 for one application in interference.

See MPEP § 806.04(h) to § 806.04(i) for species and genus in separate applications.

Wherever appropriate, such conflicting applications should be joined. This is particularly true, where the two or more applications are due to, and consonant with, a requirement to restrict which the examiner now considers to be improper.

Form paragraph 8.29 should be used when the conflicting claims are identical or conceded by applicant to be not patentably distinct.

¶ 8.29 Conflicting Claims, Copending Applications

Claim [1] of this application conflict with claim [2] of Application No. [3]. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Examiner Note:

This paragraph is appropriate only when the conflicting claims are patentably distinct.

822.01 Copending Before the Examiner

37 CFR 1.78. Claiming benefit of earlier filing date and cross-references to other applications.

(b) Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

37 CFR 1.130. Affidavit or declaration to disqualify commonly owned patent or published application as prior art.

(b) When an application or a patent under reexamination claims an invention which is not patentably distinct from an

invention claimed in a commonly owned patent with the same or a different inventive entity, a double patenting rejection will be made in the application or a patent under reexamination. A judicially created double patenting rejection may be obviated by filing a terminal disclaimer in accordance with § 1.321(c).

Where claims in one application are unpatentable over claims of another application of the same inventive entity (or different inventive entity with common ownership) because they recite the same invention, a complete examination should be made of the claims of each application and all appropriate rejections should be entered in each application, including rejections based upon prior art. The claims of each application may also be rejected on the grounds of provisional double patenting on the claims of the other application whether or not any claims avoid the prior art. Where appropriate, the same prior art may be relied upon in each of the applications. See also MPEP § 804.01 and § 822.

ONLY PROVISIONAL DOUBLE PATENTING REJECTION REMAINING IN ONE APPLICATION

The “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in one of the applications. If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent. See also MPEP § 804.01 and § 822.

ONLY PROVISIONAL DOUBLE PATENTING REJECTIONS REMAINING IN BOTH APPLICATIONS

If the “provisional” double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the



other application as a "provisional" double patenting rejection which will be converted into a double patenting rejection when the one application issues as a patent.

823 Unity of Invention Under the Patent Cooperation Treaty

See Chapter 1800 for a detailed discussion of unity of invention under the Patent Cooperation Treaty (PCT).



¶ 8.06 Claims Stand Withdrawn Without Traverse

Claim [1] withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected [2], there being no allowable generic or linking claim. Election was made without traverse in Paper No. [3].

Examiner Note:

In bracket 2, insert --invention--, or --species--.

This will show that applicant has not retained the right to petition from the requirement under 37 CFR 1.144.

Under these circumstances, when the application is otherwise ready for issue, the claims to the nonelected invention, including nonelected species, may be canceled by an examiner's amendment, and the application passed to issue. However, where the application contains an allowed generic claim, and applicant has not been previously notified as to the allowance of a generic claim, the examiner must, prior to canceling the nonelected claims, notify applicant of the allowance of a generic claim and give applicant a time limit of 1-month (not less than 30 days) to conform all of the claims to the nonelected species to fully embrace an allowed generic claim. See MPEP § 809.02(c). The examiner's amendment should include form paragraph 8.07.

¶ 8.07 Ready for Allowance Without Traverse

This application is in condition for allowance except for the presence of claim [1] to [2] nonelected without traverse. Accordingly, claim [3] been canceled.

Examiner Note:

In bracket 2, insert --an invention--, --inventions--, --a species--, or --species--.

821.03 Claims for Different Invention Added After an Office Action

Claims added by amendment following action by the examiner, MPEP § 818.01, § 818.02(a), to an invention other than previously claimed, should be treated as indicated by 37 CFR 1.145.

37 CFR 1.145. Subsequent presentation of claims for different invention.

If, after an office action on an application, the applicant presents claims directed to an invention distinct from and independent of the invention previously claimed, the applicant will be required to restrict the claims to the invention previously claimed

if the amendment is entered, subject to reconsideration and review as provided in §§ 1.143 and 1.144

The action should include form paragraph 8.04.

¶ 8.04 Election by Original Presentation

Newly submitted claim [1] directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: [2]

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim [3] withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Of course, a complete action on all claims to the elected invention should be given.

Note that the above practice is intended to have no effect on the practice stated in MPEP § 2303.

An amendment canceling all claims drawn to the elected invention and presenting only claims drawn to the nonelected invention should not be entered. Such an amendment is nonresponsive. Applicant should be notified by using form paragraph 8.26.

¶ 8.26 Canceled Elected Claims, Non-Responsive

The amendment filed on [1] canceling all claims drawn to the elected invention and presenting only claims drawn to a non-elected invention is non-responsive (MPEP § 821.03). The remaining claims are not readable on the elected invention because [2].

Since the above-mentioned amendment appears to be a *bona fide* attempt to reply, applicant is given a TIME PERIOD of ONE (1) MONTH or THIRTY (30) DAYS, whichever is longer, from the mailing date of this notice within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD UNDER 37 CFR 1.136(a) ARE AVAILABLE.

821.04 Rejoinder

Where product and process claims drawn to independent and distinct inventions are presented in the same application, applicant may be called upon under 35 U.S.C. 121 to elect claims to either the product or process. See MPEP § 806.05(f) and § 806.05(h). The claims to the nonelected invention will be withdrawn from further consideration under 37 CFR 1.142. See MPEP § 809.02(c) and § 821 through § 821.03. However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Where the application as originally filed discloses the product and the process for making and/or using the product, and only claims directed to the product are presented for examination, when a product claim is found allowable, applicant may present claims directed to the process of making and/or using the patentable product by way of amendment pursuant to 37 CFR 1.121. In view of the rejoinder procedure, and in order to expedite prosecution, applicants are encouraged to present such process claims, preferably as dependent claims, in the application at an early stage of prosecution. Process claims which depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance. Amendments submitted after final rejection are governed by 37 CFR 1.116. Process claims which do not depend from or otherwise include the limitations of the patentable product will be withdrawn from consideration, via an election by original presentation (see MPEP § 821.03). Amendments submitted after allowance are governed by 37 CFR 1.312. Process claims which depend from or otherwise include all the limitations of an allowed product claim and which meet the requirements of 35 U.S.C. 101, 102, 103, and 112 may be entered.

Where applicant voluntarily presents claims to the product and process in separate applications (i.e., no restriction requirement was made by the Office), and one of the applications issues as a patent, the remaining application may be rejected under the doctrine of obviousness-type double patenting, where appropriate (see MPEP § 804 - § 804.03), and applicant may overcome the rejection by the filing of a terminal disclaimer under 37 CFR 1.321(c) where appropriate. Similarly, if copending applications separately present product and process claims, provisional obviousness-type double patenting rejections should be made where appropriate. However, once a determination as to the patentability of the product has been reached any process claim which contains limitations identical to the allowed/allowable product should not be rejected over prior art without consultation with a Technology Center Director.

Where product and process claims are presented in a single application and that application qualifies under the transitional restriction practice pursuant to 37 CFR 1.129(b), applicant may either: (A) elect the

invention to be searched and examined and pay the fee set forth in 37 CFR 1.17(s) and have the additional inventions searched and examined under 37 CFR 1.129(b)(2); or (B) elect the invention to be searched and examined and not pay the additional fee (37 CFR 1.129(b)(3)). Where no additional fee is paid, if the elected invention is directed to the product and the claims directed to the product are subsequently found patentable, process claims which either depend from or include all the limitations of the allowable product will be rejoined. If applicant chooses to pay the fees to have the additional inventions searched and examined pursuant to 37 CFR 1.129(b)(2) even if the product is found allowable, applicant would not be entitled to a refund of the fees paid under 37 CFR 1.129(b) by arguing that the process claims could have been rejoined. 37 CFR 1.26(a) states that “[T]he Commissioner may refund any fee paid by mistake or in excess of that required. A change of purpose after the payment of a fee...will not entitle a party to a refund of such fee...” In this case, the fees paid under 37 CFR 1.129(b) were not paid by mistake nor paid in excess, therefore, applicant would not be entitled to a refund.

In the event of rejoinder, the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. If the application containing the rejoined claims is not in condition for allowance, the subsequent Office action may be made final, or, if the application was already under final rejection, the next Office action may be an advisory action.

Form paragraphs 8.42 through 8.44 should be used to notify applicant of the rejoinder of process claims which depend from or otherwise include all the limitations of an allowable product claim.

¶ 8.42 Rejoinder of Less Than All Process Claims

Claim [1] directed to an allowable product. Pursuant to the procedures set forth in the *Official Gazette* notice dated March 26, 1996 (1184 O.G. 86), claim [2], directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, [3] now subject to being rejoined. Process claim [4] hereby rejoined and fully examined for patentability under 37 CFR 1.104. In accordance with the *Official Gazette* notice, *supra*, process claim [5], which [6] not depend from or otherwise include all the limitations of the allowable product, [7] NOT been rejoined.

Examiner Note:

1. If ALL previously withdrawn claims are being rejoined, then form paragraph 8.43 should be used instead of this form paragraph.
2. If other non-process claims are present and are NOT being rejoined, use form paragraph 8.44 instead of this form paragraph.
3. In bracket 1, insert the claim number(s) of the allowable product claims followed by either -- is-- or -- are--.
4. In bracket 2, insert the claim number(s) of ALL process claims previously withdrawn from consideration.
5. In bracket 3, insert either --is-- or --are--.
6. In bracket 4, insert the number(s) of the rejoined process claims.
7. In bracket 5, insert the number(s) of the process claims NOT being rejoined followed by either -- is-- or -- are--.
8. In bracket 6, insert --do-- or --does--.
9. In bracket 7, insert --has-- or --have--.
10. If rejoinder occurs after the first Office action on the merits and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final since the new ground of rejection was necessitated by applicant's reply.

¶ 8.43 Rejoinder of All Previously Withdrawn Claims

Claim [1] directed to an allowable product. Pursuant to the procedures set forth in the *Official Gazette* notice dated March 26, 1996 (1184 O.G. 86), claim [2], directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, [3] now subject to being rejoined. Claim [4] hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Paper No. [5] is hereby withdrawn.

Examiner Note:

1. If LESS THAN ALL previously withdrawn process claims are being rejoined, then form paragraph 8.42 should be used instead of this form paragraph. If LESS THAN ALL previously withdrawn claims are being rejoined, then form paragraph 8.44 should be used instead of this form paragraph.
2. In bracket 1, insert the claim number(s) of the allowable product claim(s) followed by either -- is-- or -- are--.
3. In bracket 2, insert the claim number(s) of the process claim(s) previously withdrawn from consideration.
4. In bracket 3, insert either --is-- or --are--.
5. In bracket 4, insert the number(s) of the process claims being rejoined (should correspond to bracket 2 insert).
6. If rejoinder occurs after the first Office action on the merits and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final since the new ground of rejection was necessitated by applicant's reply.

¶ 8.44 Rejoinder of Process Claims, Other Claims Present and Not Rejoined

Claim [1] directed to an allowable product. Pursuant to the procedures set forth in the *Official Gazette* notice dated March 26,

1996 (1184 O.G. 86), claim [2], directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, [3] now subject to being rejoined. Process claim [4] hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claim [5], not directed to the process of making or using the patentable product, will not be rejoined.

Examiner Note:

1. If LESS THAN ALL previously withdrawn process claims are being rejoined, then form paragraph 8.42 should be used instead of this form paragraph. If ALL previously withdrawn claims are being rejoined then form paragraph 8.43 should be used instead of this form paragraph.
2. In bracket 1, insert the claim number(s) of the allowable product claim(s) followed by either -- is-- or -- are--.
3. In bracket 2, insert the claim number(s) of the process claim(s) previously withdrawn from consideration.
4. In bracket 3, insert either --is-- or --are--.
5. In bracket 4, insert the number(s) of the process claims being rejoined (should correspond to bracket 2 insert).
6. In bracket 5, insert the number(s) of all previously withdrawn claims which are not being rejoined.
7. If rejoinder occurs after the first Office action on the merits and if any of the rejoined claims are unpatentable, e.g., if a rejection under 35 U.S.C. 112, first paragraph is made, then the next Office action may be made final since the new ground of rejection was necessitated by applicant's reply.

See MPEP § 706.02(n) for the applicability of 35 U.S.C. 103(b) to biotechnological processes and compositions of matter.

See MPEP § 2116.01 for guidance on the treatment of process claims which make or use a novel, nonobvious product.

See MPEP § 806.05(c) for rejoinder of restricted combination/subcombination inventions when an evidence claim is found to be unallowable, and see MPEP § 809 and § 809.04 for rejoinder of restricted inventions when a linking claim is found allowable.

822 Claims to Inventions That Are Not Distinct in Plural Applications of Same Inventive Entity

The treatment of plural applications of the same inventive entity, none of which has become a patent, is treated in 37 CFR 1.78(b) as follows:

- (b) Where two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application.

FULL TEXT OF CASES (USPQ2D)

All Other Cases

In re Ochiai (CA FC) 37 USPQ2d 1127 In re Ochiai

**U.S. Court of Appeals Federal Circuit
37 USPQ2d 1127**

**Decided December 11, 1995
No. 92-1446**

Headnotes**PATENTS****1. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions (§ 115.0903.03)****Patent construction -- Claims -- Process (§ 125.1309)**

Application claim for process of making particular cephem compound having antibiotic properties, using particular type of organic acid first disclosed in parent application, is not prima facie obvious over prior art of record, since obviousness inquiry of 35 USC 103 requires comparison of claim's "subject matter as a whole" with prior art "to which said subject matter pertains," since process invention recited in claim specifically

Page 1128

requires use of new, unobvious acid as one of starting materials, and since it would not have been obvious to those of ordinary skill in art to choose particular acid required by claim, which was unknown but for its disclosure in application, as acylating agent for

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known amine; characterization of specifically claimed acid as "similar" to or "slightly different" from those used in prior art cannot establish obviousness of use of starting material that is new and nonobvious, both in general and in claimed process.

2. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

Patent construction -- Claims -- Process (§ 125.1309)

There is no per se rule that process claim is obvious if prior art references disclose same general process using "similar" starting materials; application of such rule is improper, since it sidesteps particularized obviousness inquiry required by 35 USC 103 and necessarily produces erroneous results.

3. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

No per se rules of obviousness have been established by precedent, and reliance on any such rules that eliminate need for fact-specific analysis of claims and prior art is legally incorrect and must cease, since use of per se rules in obviousness determination is inconsistent with 35 USC 103, which entitles applicant to issuance of otherwise proper patent unless Patent and Trademark Office establishes that invention, as claimed in application, is obvious over cited prior art, based on specific comparison of that prior art with claim limitations.

Case History and Disposition:

Page 1128

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences; 24 USPQ2d 1265 .

Patent application of Michihiko Ochiai, Taiiti Okada, Osami Aki, Akira Morimoto, Kenji Kawakita, and Yoshihiro Matsushita, serial no. 07/462,492, filed January 8, 1990. from decision upholding examiner's rejection of claims 6 through 10, applicants appeal. Reversed.

Attorneys:

Harold C. Wegner, Herbert I. Cantor, and Douglas P. Mueller, of Wegner, Cantor, Mueller & Player, Washington, D.C.; Don J. Pelto, of

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Foley & Lardner, Washington, for appellant.

**Fred E. McKelvey, solicitor, U.S. Patent and Trademark Office,
Nancy J. Linck, solicitor, Lee E. Barrett, John W. Dewhirst, and
Richard E. Schafer, associate solicitors, and Albin F. Drost, deputy
solicitor, for PTO.**

Judge:

**Before Archer, chief judge, * Michel, circuit judge, and Carrigan, district
judge.****

Opinion Text

Opinion By:

Per curiam.

This appeal is from the July 8, 1992, decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board) affirming the examiner's rejection of claims 6 through 10 of Michihiko Ochiai *et al.*'s (collectively "Ochiai") application serial no. 07/462,492, claiming priority from parent application serial no. 642,356, filed December 19, 1975, now U.S. Patent No. 4,098,888 (methods for the manufacture of cephems). *Ex parte Ochiai*, 24 USPQ2d 1265 (Bd. Pat. App. & Int. 1992). The real party in interest is Takeda Chemical Industries, Ltd., the assignee of any patent issuing from the application.

The rejection of the above claims was predicated on an asserted view of the law of obviousness, per 35 U.S.C. Section 103, in view of the combined teaching of six references. 1 Because, under the legally correct method for determining obviousness, the claimed process is not obvious in view of the cited prior art references, we reverse.

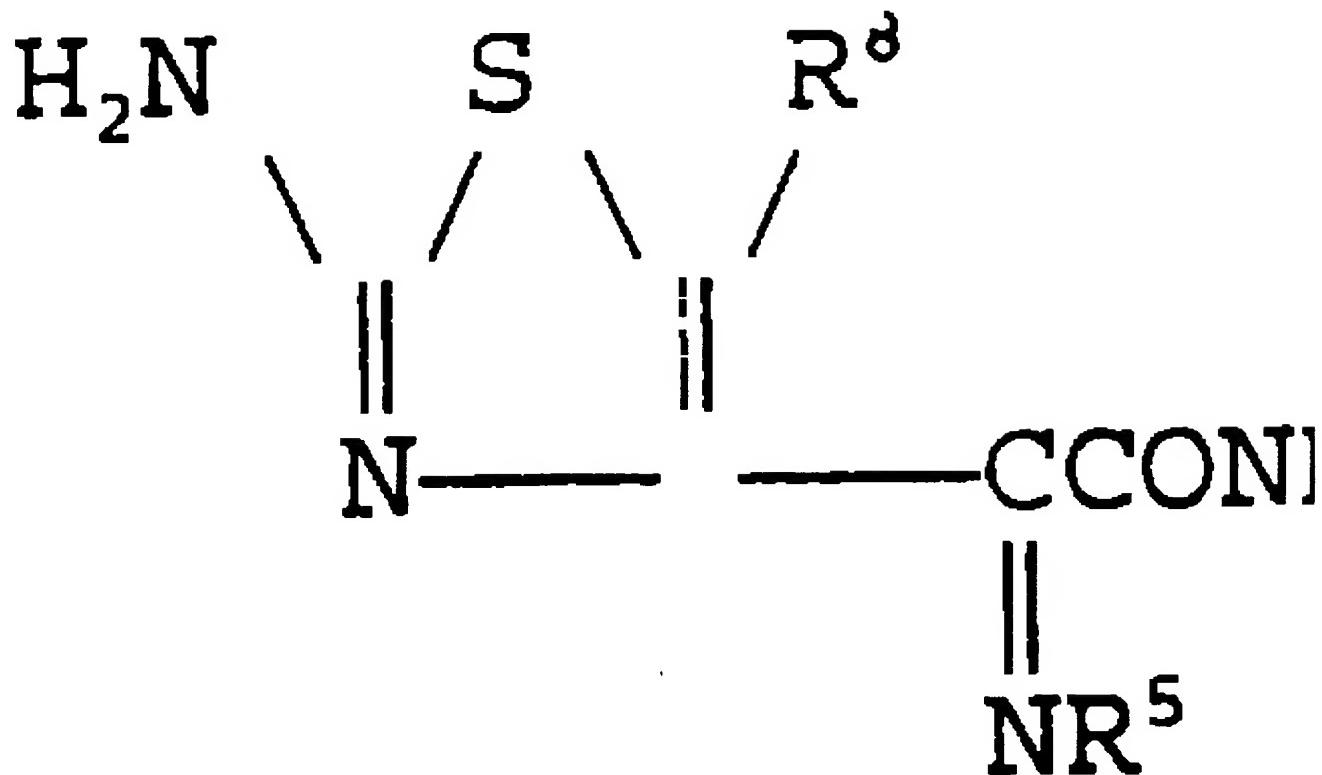
The Invention

Ochiai's application is directed to a process for using an acyl side chain from a particular type of organic acid having a 2-aminothiazolyl group, and a particular type of amine to make a particular cephem compound having antibiotic properties.

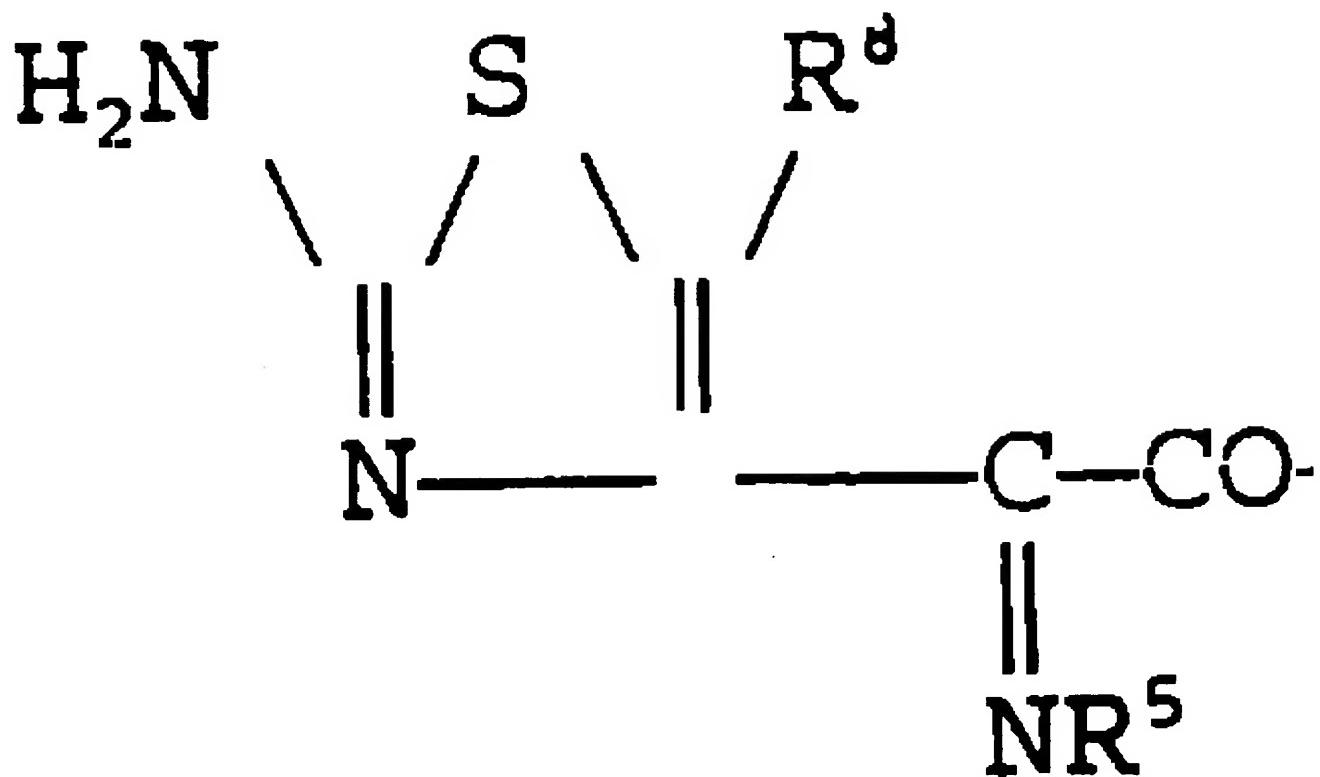
Page 1129

Claim 6, the principal claim on appeal, 2 is as follows:

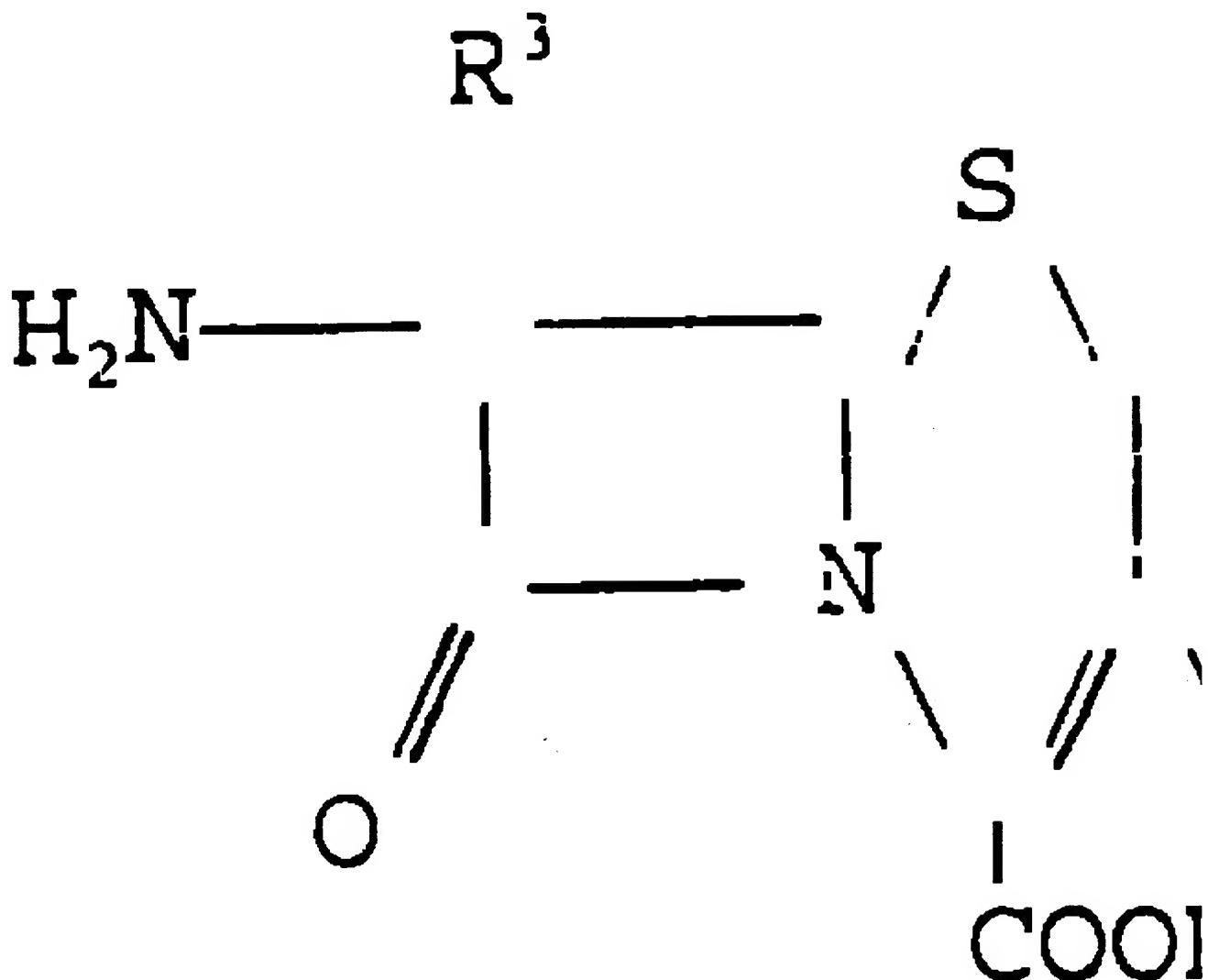
6. A process for preparing a cephem compound of the formula:



wherein R^3 is hydrogen or methoxy, R^4 is hydrogen or a residue of a nucleophilic compound, R^5 is hydroxyl or a protected hydroxyl, and R^5 is hydrogen or a halogen, or a pharmaceutically acceptable salt or ester thereof, which comprises introducing an acyl group of the formula:



wherein R^5 and R^8 are as defined above into the amino group of the molecule of the formula:



wherein R^3 and R^4 are as defined above or a salt or ester thereof.

Id. at 1266.

Ochiai's U.S. Patent No. 4,298,606 covers the cephem compound resulting from the process of claim 6, and Ochiai's U.S. Patent No. 4,203,899 covers the organic acid used in the process of claim 6. *Id.* at 1267. In other words, viewed as of the time the claimed process was invented, claim 6 recites a process of using a new, nonobvious acid to make a new, nonobvious cephem. The '606 and '899 patents, like the application at bar, claim priority from the December 1975 parent application.

The Rejection

The examiner rejected claims 6 through 10 as obvious in light of the combined teaching of the six references noted above. All six references, as Ochiai acknowledges, teach the use of a type of acid to make a type of cephem by a standard acylation reaction with the very same amine recited in claim 6. The examiner explained the rejections thusly in his

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answer to Ochiai's appeal to the Board:

It must again be stressed that the citation of six references is to demonstrate convincingly that a *standard*, *conventional* process of preparing cephalosporin compounds is being claimed. The *only* difference between what is being claimed and the prior art is the selection of a *slightly* different acylation agent [*i.e.* , acid] to result in a slightly different final product. The *closest* prior art of the six references is represented by the Cook et al. 4,024,133 and, Gregson et al. patent 4,024,134. These two references use [sic, are] quite similar in their disclosure, Cook being the *most* [sic, more] relevant. Both of these references *generically* disclose the "2-amino-thiazolyl" group which appellants seek to introduce. . . .

...
The examiner recognizes that the *specific* "2 amino thiazolyl" moiety has *not* been *specifically* named in [the] Cook et al [.] patent. However, Cook et al. when viewed from the standpoint of one skilled in the art would recognize the use of "2-aminothiazolyl" if the final products sought were to contain this moiety. This merely states the obvious. . . .

...
The facts presented here are *identical* to those that occurred in the Durden decision (In re Durden 226 USPQ 359). The *acylating* agent herein being used has been patented by appellants, see Ochiai et al. 4,203,899. The final products have also been patented by appellants which appellants acknowledge, brief page 5 footnote 4.

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The *only* difference between the facts in Durden those Durden [sic] and the instant situation is that appellants have not *admitted* on the record that the process is obvious. Appellants seek to distinguish the Durden decision based on this difference. However, the Durden decision is believed to be controlling because of the *reasoning* used therein and not an admission or lack of admission of the obviousness of the process. The references discussed above abundantly demonstrate the *routineness* of the claimed process. Thus, the Court rejected the argument that a conventional manipulation or reaction was *unobvious* "not-withstanding the specific starting material or resulting product or both, is not to be found in the prior art".

(Emphasis in original). Importantly, the examiner conceded the total absence from the prior art of both the acid used and the cephem made in the process recited in claim 6. In addition, the examiner discussed no references containing any suggestion or motivation either (a) to reject known acids and select instead the particular one used in claim 6, or (b) to obtain the particular cephem made according to the process of claim 6.

On appeal, the Board affirmed the examiner's rejection. After reviewing the examiner's reliance on *In re Durden* , 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985), and the "standard" nature of the acylation reaction disclosed in the rejected claims, the Board acknowledged Ochiai's contention that the fact that "neither the final product nor the method of introducing the particular [acid] component were known, obvious or even remotely suggested in the prior art . . . should be dispositive of the obviousness of the invention" recited in claim 6. *Ochiai* , 24 USPQ2d at 1267. The Board did not, however, find Ochiai's contention persuasive. According to the Board,

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[w]e are not here concerned with the patentability of the starting materials, the final compounds or other processes of making the [cephem] compounds. We are concerned only with the claimed process and the patentability thereof. Cases such as *In re Larsen*, 292 F.2d 531, 130 USPQ 209 (CCPA 1961); *In re Albertson*, 332 F.2d 379, 141 USPQ 730 (CCPA 1964) and, particularly, *In re Durden*, *supra*, all of which were directed to processes of making chemical compounds, are controlling herein. . . . In each case, a material A, either known or novel, was subjected to a standard process of reacting with a standard reactant, B, in order to produce the result expected from the reaction of A with B. Indeed in *Albertson* as in the instant case, the only manipulative step of the process is that which is embodied in the word "reacting."

Id. The Board also rejected Ochiai's assertion that cases such as *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990), *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974), and *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973), are in tension with *Durden* and *Albertson* and counsel allowance of the rejected claims. Distinguishing *Pleuddemann*, *Mancy*, and *Kuehl* as "method of using" rather than "method of making" cases, the Board summarized its decision as follows:

In the case before us, appellants have admitted the claims are directed to a process of making a desired AB product. The process steps, "introducing" A into AB or "reacting" A with B are standard processes used by practitioners in the prior art for reacting similar A moieties with the same B moiety. We are in agreement with the examiner that there is nothing unobvious in the particular *process* chosen and claimed by the appellants.

Ochiai, 24 USPQ2d at 1270 (emphasis in original).

Ochiai appeals, contending that both the examiner and the Board failed to apply the proper test for obviousness established by *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), and its progeny. Specifically, according to Ochiai, both the examiner and the Board, on the assumption that our decision in *Durden* controlled the outcome of the instant case, failed to weigh the specific differences between the claimed invention -- with *all* its limitations -- and the prior art references, the so-called "second *Graham* factor." See *id.* at 17 ("Under Section 103 . . . differences between the prior art and the claims at issue are to be ascertained [.]"). In addition, Ochiai contends that the decisions in *Mancy* and *Kuehl*, which, like all Court of Customs and Patent Appeals decisions, were in banc, limit the decision in *Albertson* to its facts.

The Solicitor, while defending the correctness of the Board's conclusion and, unlike the Board itself, doing so in the familiar terms of *Graham*, also asserts that a supposed irreconcilable conflict in our cases -- between *Albertson* and *Durden*, on the one hand, and *Pleuddemann*, on the other -- "makes it very difficult for patent attorneys to give cogent advice to clients or for patent examiners to render consistent decisions on the patentability (under Section 103) of processes involving the use of new and unobvious starting materials." Unlike Ochiai, however, the Solicitor

asks us to take the opportunity to reaffirm the vitality of *Albertson* and *Durden* in the course of deciding this appeal.

The Issue

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The issue before this court is whether the Board erred in upholding the examiner's rejection of claim 6 as obvious under 35 U.S.C. Section 103 in view of *Larsen*, *Albertson*, and *Durden* as interpreted by the PTO when neither the particular acid used nor the particular cephem produced is either taught or suggested by the art that predates the parent application.

The Analysis

The test of obviousness *vel non* is statutory. It requires that one compare the claim's "subject matter as a whole" with the prior art "to which said subject matter pertains." 35 U.S.C. Section 103. The inquiry is thus highly fact-specific by design. This is so "whether the invention be a process for making or a process of using, or some other process." *Kuehl*, 475 F.2d at 665, 177 USPQ at 255. When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

[1] Applying this statutory test to the art of record, we conclude that Ochiai's process invention as claimed is not *prima facie* obvious. The process invention Ochiai recites in claim 6 specifically requires use of none other than its new, nonobvious acid as one of the starting materials. One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure in the '492 application. As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, "one cannot choose from the unknown." *Mancy*, 499 F.2d at 1293, 182 USPQ at 306. 3

In addition, although the prior art references the examiner discussed do indeed teach the use of various acids to make various cepheums, they do not define a class of acids the knowledge of which would render obvious the use of Ochiai's specifically claimed acid. 4 The Board noted that Ochiai's specifically claimed acid is "similar" to the acids used in the prior art. Likewise, the examiner asserted that the claimed acid was "slightly different" from those taught in the cited references. Neither characterization, however, can establish the obviousness of the use of a starting material that is new and nonobvious, both in general and in the claimed process. The mere chemical possibility that one of those prior art acids could be modified such that its use would lead to the particular cephem recited in claim 6 does not make the process recited in claim 6 obvious "unless the prior art suggested the desirability of [such a] modification." *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). As we noted above, the examiner discussed no references containing any suggestion or motivation either (a) to modify known acids to obtain the particular one recited in claim 6, or (b) to obtain the particular new and nonobvious cephem produced by the process of claim 6. In short, the prior art contains nothing at all to support the conclusion that the particular process recited in claim 6 is obvious.

[2] In light of the above, the examiner's errors are evident. First, the examiner concluded that one of ordinary skill in the art would "recognize the use of 2-aminothiazolyl" if the final products sought were to contain this moiety." The prior art, however, contains

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nothing at all to suggest that one seek this concededly nonobvious final product. The examiner erred by indulging in an essentially hindsight comparison of the functioning of the new acid in claim 6 as a precursor to the claimed cephem with that of other acids in the prior art processes that produced other cepheems. Such a comparison uses Ochiai's specification as though it were

Page 1132

prior art in order to make the claim to a method that uses the nonobvious acid to make the nonobvious cephem appear to be obvious. Second, the examiner incorrectly drew from *Durden*, a case turning on specific facts, a general obviousness rule: namely, that a process claim is obvious if the prior art references disclose the same general process using "similar" starting materials. No such *per se* rule exists. Mere citation of *Durden*, *Albertson*, or any other case as a basis for rejecting process claims that differ from the prior art by their use of different starting materials is improper, as it sidesteps the fact-intensive inquiry mandated by section 103. In other words, there are not "*Durden* obviousness rejections" or "*Albertson* obviousness rejections," but rather only section 103 obviousness rejections.

The Board essentially repeated the examiner's error of sidestepping the particularized inquiry required by section 103 by grounding the rejection on the supposedly "controlling" effect of "[c]ases such as *In re Larsen*, *In re Albertson*, and, particularly, *In re Durden*, all of which were directed to processes of making chemical compounds." *Ochiai*, 24 USPQ2d at 1267 (citations omitted). After categorizing the process recited in claim 6 as a "process of making" rather than as a "process for using," the Board reached its conclusion according to the following syllogism: (a) "process of making" claims have led to rejections, as in *Larsen*, *Albertson*, and *Durden*, whereas "process for using" claims have led to allowances, as in *Kuehl*, *Mancy*, and *Pleuddemann*; (b) Ochiai's claim is directed to a "process of making"; (c) therefore, the rejection should be affirmed. *Id.* at 1268-70. This method of analysis is founded on legal error because it substitutes supposed *per se* rules for the particularized inquiry required by section 103. It necessarily produces erroneous results. Moreover, the Board indulged a non sequitur when it grounded its conclusion of obviousness on the assertion that the starting materials recited in claim 6 are "similar" to those of the prior art. The recited acid is nonobvious, having itself been patented based on the parent application. Nor did the Board justify its characterization of "similar [ity]" in any other manner. Similarity is, as we noted above, not necessarily obviousness.

The Alleged Conflict in Our Case Law

Both the Solicitor and Ochiai devote substantial portions of their briefs to purported demonstrations that our precedents on the obviousness *vel non* of chemical processes are, if not in conflict, at least in severe tension with one another and thus create unnecessary confusion. Both parties identify the same two sets of three cases as presenting the conflict: *Larsen*, *Albertson*, and *Durden*, upholding rejections on appeal, are said to be inconsistent with *Kuehl*, *Mancy*, and *Pleuddemann*, reversing rejections on appeal. While we agree that *some* generalized commentary found within several of these decisions may present minor tensions, both Ochiai and the

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Solicitor draw far too bleak a picture of the state of our case law. Other language in these cases, like their actual holdings, obviates any real inconsistency.

In *Albertson*, the court "reiterate [d] that all of the evidence must be considered on the 'subject matter as a whole,' from the viewpoint of one skilled in the art, in the determination of obviousness, and not simply the patentability of one of the starting reactants in a process." *Albertson*, 332 F.2d at 382, 141 USPQ at 732. Thus, the Board in this case looked to the general result in *Albertson* while ignoring the *Albertson* court's explicit methodology. Every subsequent case that the parties discuss has been grounded on the same analytic principle: namely, that section 103 requires a fact-intensive comparison of the claimed process with the prior art rather than the mechanical application of one or another *per se* rule. See *Pleuddemann*, 910 F.2d at 827, 15 USPQ2d at 1741 ("We repeat that the controlling law is in Section 103 of the statute, which must be applied to the facts of this case."); *Durden*, 763 F.2d at 1411, 226 USPQ at 362 ("Our function is to apply, in each case, Section 103 as written to the facts of disputed issues, not to generalize or make rules for other cases which are unforeseeable."); *Mancy*, 499 F.2d at 1292, 182 USPQ at 305 ("[T]he statutory standard of Section 103 for determining obviousness of an invention is whether in view of the prior art the invention as a whole would have been obvious at the time it was made."); *Kuehl*, 475 F.2d at 665, 177 USPQ at 255 ("The test of unobviousness is a statutory test and

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requires comparison of the invention with the prior art in each case. . . ."). As a consequence, these cases do not -- indeed, *cannot* -- present or create conflicting legal rules. They present, instead, applications of a unitary legal regime to different claims and fields of art to yield particularized results. It is thus surprising that the Board relies on *Durden* for a general rule when the *Durden* court expressly cautioned the bar "not to generalize or make rules for other cases."

Because the regime of section 103, much like the Fourth Amendment proscriptions against "unreasonable" searches and warrants issued upon less than "probable cause," mandates that legal outcomes turn on the close analysis of facts, reasonable persons may well disagree about the outcome of a given obviousness determination. These disagreements over the application of a legal rule can, however, be transformed into perceived "irreconcilable conflicts" between legal rules only when, as occurred here, examiners, members of the Board, and patent lawyers purport to find competing *per se* rules in our precedents and argue for rejection or allowance of a particular claim accordingly. We acknowledge that some generalized commentary found in these cases reviewing rejections of claims directed to chemical processes may, if viewed in isolation, have inadvertently provided encouragement to those who desire *per se* rules in this area. For example, one case includes an extensive discussion of the conceptual link between the obviousness *vel non* of a chemical composition and the obviousness *vel non* of a process for making the composition.⁶ Such discussion, while entirely accurate, may have contributed to the erroneous view that one may determine the obviousness of a chemical process merely by determining whether it is a process for making a composition. As the cases noted above make clear, however, this is not and has

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never been the law of section 103. Indeed, *Durden*, the very case relied on by the examiner and the Board for a purported *per se* rule, clearly states that there are no such *per se* rules.

[3] The use of *per se* rules, while undoubtedly less laborious than a searching comparison of the claimed invention -- including all its limitations -- with the teachings of the prior art, flouts section 103 and the fundamental case law applying it. *Per se* rules that eliminate the need for fact-specific analysis of claims and prior art may be administratively convenient for PTO examiners and the Board. Indeed, they have been sanctioned by the Board as well. But reliance on *per se* rules of obviousness is legally incorrect and must cease. Any such administrative convenience is simply inconsistent with section 103, which, according to *Graham* and its progeny, entitles an applicant to issuance of an otherwise proper patent unless the PTO establishes that the invention *as claimed* in the application is obvious over cited prior art, based on the specific comparison of that prior art with claim limitations: We once again hold today that our precedents do not establish any *per se* rules of obviousness, just as those precedents themselves expressly declined to create such rules. Any conflicts as may be perceived to exist derive from an impermissible effort to extract *per se* rules from decisions that disavow precisely such extraction.

In sum, as we clearly indicated in *In re Dillon*, a recent in banc decision, " [w]hen any applicant properly presents and argues suitable method claims, they should be examined in light of all . . . relevant factors, free from any presumed controlling effect of *Durden* " or any other precedent. 919 F.2d 688, 695, 16 USPQ2d 1897, 1903 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991). Having compared Ochiai's claims, limited as they are to the use of a particular nonobvious starting material for making a particular nonobvious end product, to the prior art of record, we reverse the rejection of claims 6 through 10 as an incorrect conclusion reached by incorrect methodology. *Reversed*.

Footnotes

Footnote 1. The references are as follows: U.S. Patent No. 3,167,549 to Hoover; U.S. Patent No. 3,338,897 to Takano *et al.*; U.S. Patent No. 3,360,515 to Takano *et al.*; U.S. Patent No. 4,024,133 to Cook *et al.*; U.S. Patent No. 4,024,134 to Gregson *et al.*; and Flynn, *Cephalosporin and Penicillins* 83-91 (1972). *Ochiai*, 24 USPQ2d at 1266.

Footnote 2. Because Ochiai did not argue the separate patentability of claims 6 through 10 before the Board, all the claims stand (or fall) together. *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1900 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991); *In re Kroekel*, 803 F.2d 705, 709, 231 USPQ 640, 642-43 (Fed. Cir. 1986).

Footnote 3. In *Mancy*, the applicant claimed a process for using a newly discovered strain of the microorganism *Streptomyces* to produce a known antibiotic by means of conventional aerobic cultivation. 499 F.2d at 1290, 182 USPQ at 304. The examiner rejected the claim, and the Board affirmed the rejection. The court reversed, having

concluding that

[w]ithout *Streptomyces bifurcatus*, strain DS 23,219 , knowledge of which is supplied [only] by appellants' application and availability of which is supplied by appellants' deposit of the microorganism with the Department of Agriculture, one skilled in the art would not find it obvious to produce daunorubicin by aerobically cultivating *Streptomyces bifurcatus* .

Id. at 1292, 182 USPQ at 305.

Footnote 4. The prior art teaches the use of thienyl, pyridyl, and isothiazolyl compounds, whereas claim 6 recites the use of 2-aminothiazolyl.

Footnote 5. This is most apparent from the examiner's baffling assertions that "a standard , conventional process . . . is being claimed" and that " [t]he references . . . abundantly demonstrate the routineness of the claimed process." Because the claimed process includes as a limitation the use of an acid unknown in the prior art, the prior art can only demonstrate the routineness of a process similar to the claimed one. Similarity is, of course, not necessarily obviousness.

Footnote 6. See *Pleudemann* , 910 F.2d at 827, 15 USPQ2d at 1741 ("From the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same thing.' *In re Papesch* , 50 CCPA 1084, 315 F.2d 381, 391, 137 USPQ 43, 51 (1963). It is the properties of appellant's compounds as bonding/priming agents for certain polymers and fillers or support surfaces that give them their utility. As stated above, the compounds and their use are but different aspects of, or ways of looking at, the same invention and consequently that invention is capable of being claimed both as new compounds or as a new method or process of bonding/priming. On the other hand, a process or method of making the compounds is a quite different thing; they may have been made by a process which was new or old, obvious or nonobvious. In this respect, therefore, there is a real difference between a process of making and a process of using and the cases dealing with one involve different problems from the cases dealing with the other.").

Footnote *. Judge Archer assumed the position of Chief Judge on March 18, 1994.

Footnote **. Honorable James R. Carrigan, United States District Court for the District of Colorado, sitting by designation. Judge Carrigan retired from the federal judiciary effective August 19, 1995, and thus took no part in the disposition of this appeal.

- End of Case -

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FULL TEXT OF CASES (USPQ2D)
All Other Cases

In re Brouwer (CA FC) 37 USPQ2d 1663 In re

Brouwer

**U.S. Court of Appeals Federal Circuit
37 USPQ2d 1663**

**Decided December 13, 1995 Precedential Opinion Issued February 8,
1996
No. 92-1225**

Headnotes

PATENTS

1. Patentability/Validity -- Obviousness -- Relevant prior art -- Particular inventions (§ 115.0903.03)

Application claims for process of reacting crosslinked resin with ester of alkenesulfonic acid to make sulfoalkylated resin catalyst are not *prima facie* obvious over references cited by examiner, which teach generic reaction of compound containing active methylene group with ester of sulfonic acid, since mere fact that device or process utilizes known scientific principle does not alone make that device or process obvious, and since mere possibility that ester or active methylene group-containing compound disclosed in reference could be modified or replaced in manner that would lead to specific sulfoalkylated resin recited in claims does not render claimed process obvious absent suggestion in prior art that such modification or replacement is desirable.

2. Patentability/Validity -- Obviousness -- In general (§ 115.0901)

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Patent construction -- Claims -- Process (§ 125.1309)

Examiner erred by resting *prima facie* case of obviousness for claimed process on purportedly controlling nature of precedent, rather than on particularized findings regarding set of one or more references that would make claimed process obvious, since suitable method claims, if properly presented and argued, should be examined in light of all relevant factors, free from any presumed controlling effect of precedent.

Case History and Disposition:

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Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Dirk M. Brouwer and Elizabeth M. Van De Vondervoort, serial no. 07/098,154, filed September 18,

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1987, which is division of serial no. 831,398, filed February 20, 1986, now patent no. 4,728,695. From reconsideration decision upholding examiner's rejection of claims 8-27 in application, applicants appeal. Reversed.

Attorneys:

M.P. Haddican and Dean F. Vance, Houston, Texas, for appellant.

Fred E. McKelvey, solicitor (at the time briefs were filed), Richard E. Schafer, Teddy S. Gron, associated solicitors, Joseph G. Piccolo, assistant solicitor, Harris A. Pitlick, John W. Dewhirst, and Lee E. Barrett, PTO, for appellee.

Judge:

Before Archer, chief judge, * Michel, circuit judge, and Carrigan, district judge.**

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Opinion Text

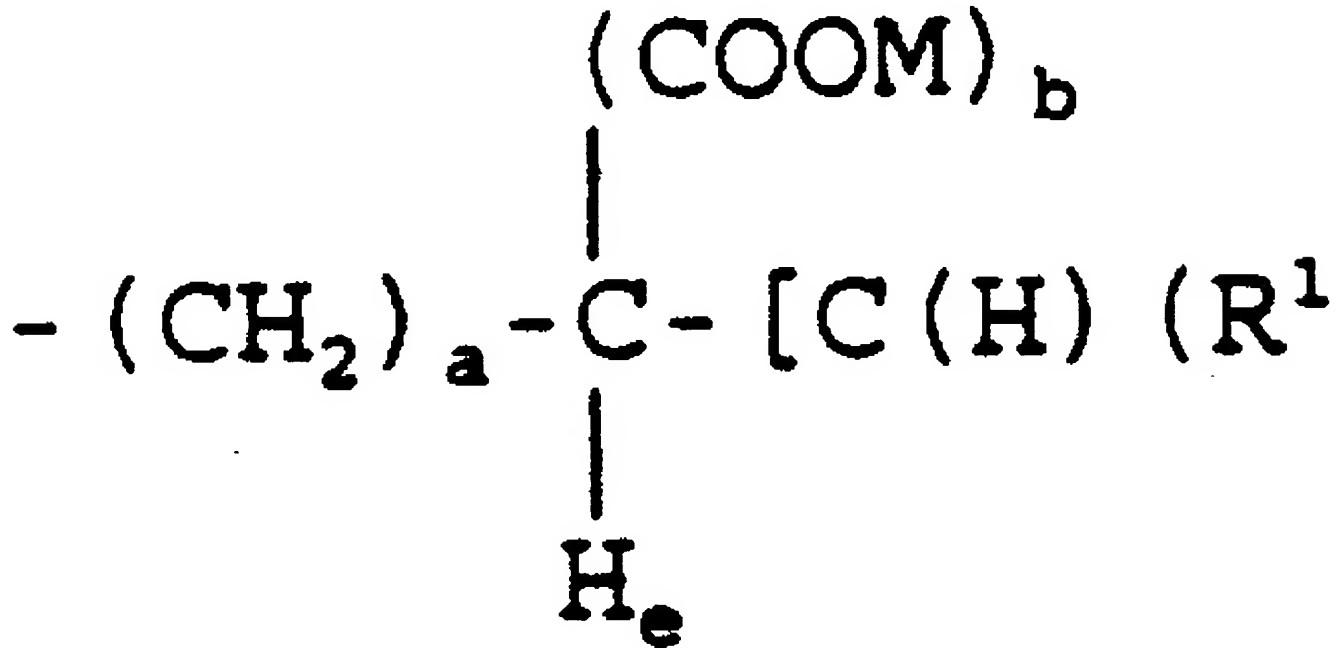
Opinion By:
Per curiam.

This appeal is from the December 9, 1991, reconsideration decision of the United States Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (Board), Appeal No. 90-1349. That decision adhered to the Board's March 18, 1991, decision affirming the examiner's rejection of claims 8 through 27 of Brouwer and Van De Vondervoort's (collectively Brouwer) application serial no. 98,154, a division of application serial no. 831,398, filed February 20, 1986, now U.S. Patent No. 4,728,695 (crosslinked resins containing thermally stable sulfonic acid groups). The real party in interest is Shell Oil Company, the assignee of any patent issuing from the application. The rejection of the above claims was predicated solely on obviousness, per 35 U.S.C. Section 103, in view of the combined teaching of two references. 1 Because, under the legally correct method for determining obviousness, the claimed process is not obvious in view of the cited prior art references, we *reverse*.

DISCUSSION *The Invention*

Brouwer's application is directed to a process for preparing sulfoalkylated polystyrene-divinylbenzene resins. Claim 8, the principal claim on appeal, 2 is as follows:

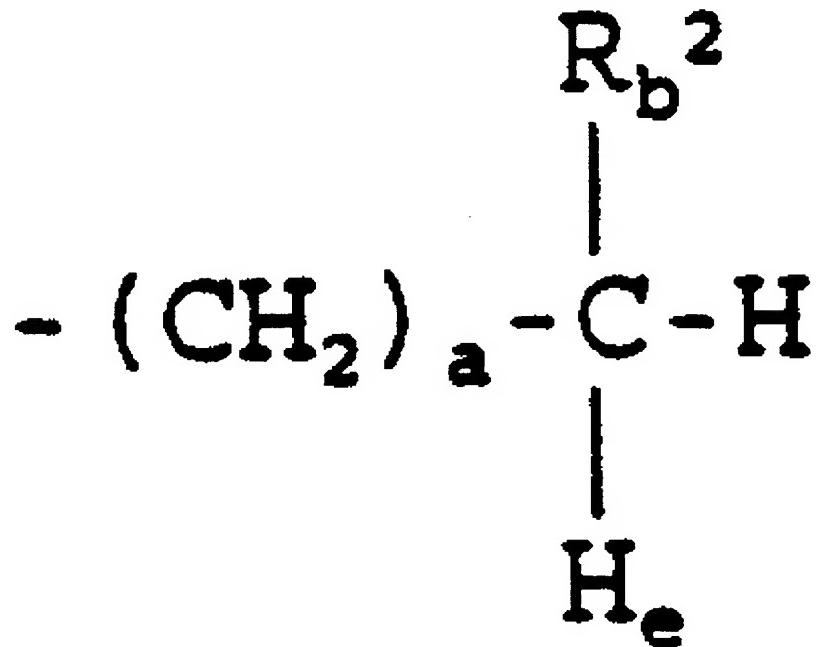
8. A process for the preparation of a catalyst comprising an aryl group having a functional substituent group of general formula



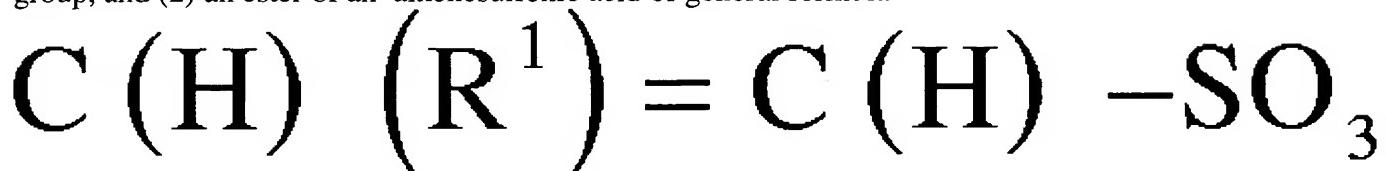
wherein a is 0 or 1, b is 1 or 2, d is 1 or 2, e is 01 or 1, $b+d+e=3$, R^1 represents H or a C1 to C4 alkyl group and M is a proton or another cation; which process comprises the steps of

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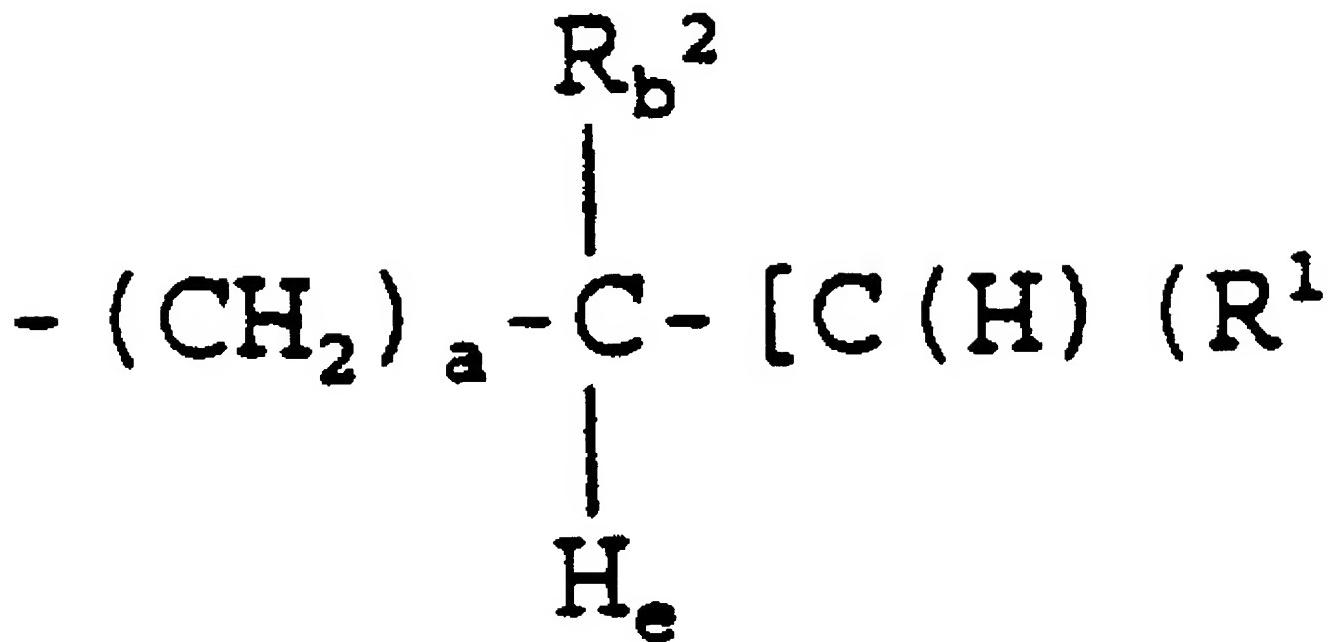
a) reacting (1) a crosslinked resin comprising at least one substituted aryl group having a functional substituent group of general formula



wherein a, b, and e have the same meaning as in general formula (I), $b+e=2$, R^2 is a -CN or a carboxyester group and if b is 2, each R^2 represents a -CN or a carboxyester group, and (2) an ester of an alkenesulfonic acid of general formula



wherein R^1 has the same meaning as in general formula (I), and R^3 is a hydrocarbyl group, under conditions suitable for the formation of an addition product of general formula



wherein a, b, d, e and R¹ have the same meaning as in general formula (I), b+d+e=3, R² has the same meaning as in

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general formula (II) and R³ has the same meaning as in general formula (III), and then (b) hydrolyzing the addition product of general formula (IV) to produce a compound having a functional group of general formula (I).

Brouwer's U.S. Patent No. 4,728,695 covers the sulfoalkylated resins resulting from the process recited in claim 8. In other words, viewed as of the time the claimed process was invented, claim 8 recites a process of reacting a crosslinked resin with an ester of an alkenesulfonic acid to make a new, nonobvious sulfoalkylated resin catalyst. The '695 patent, like the application at bar, claims priority to the February 1986 parent application.

The Rejection

The examiner rejected claims 8 through 27 in light of the combined teaching of the two references noted above. As Brouwer acknowledges, Distler teaches so-called "Michael addition" reactions 3 in which a vinylsulfonate is reacted with an active methylene group-containing compound. Distler, however, neither discloses nor suggests making a catalyst by reacting an ester of an alkenesulfonic acid with a crosslinked resin; instead, Distler discloses simple, well-defined compounds the derivatives of which would not be expected to exhibit the catalytic activity and thermal stability of the sulfoalkylated resin made according to the process of claim 8. Specifically, the crosslinked resin recited in claim 8, unlike the Distler compound having an active methylene group, has an aryl-pendant -CN or carboxyester functional group. Morrison & Boyd's *Organic Chemistry*

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broadly discloses Michael addition reactions with two simple hydrocarbons; like Distler, it neither discloses nor suggests reacting an ester of an alkenesulfonic acid with a crosslinked resin. The examiner explained his initial rejections thusly:

Process of preparing polymer by using a unsaturated compound with active methylene substrate is well known as shown by Distler or Organic Chem. Applicants' methylene unit (III) possess [es] the characteristics required to carry out reactions of the Michael-type reactions. *In re Durden*, 226 USPQ 359 .

Importantly, the examiner discussed no references containing any suggestion or motivation either (a) to use a resin-substituted methylene reactant in the generic addition reaction taught by the cited references, or (b) to obtain the specific sulfoalkylated resin catalyst made according to the process of claim 8. The examiner offered this same explanation, virtually verbatim, in both his final rejection and his answer to Brouwer's appeal to the Board.

On appeal, the Board affirmed the examiner's rejection. According to the Board, The basic difference between the claimed Michael addition reaction and reaction "(n)" disclosed on page 304 of Distler is that the latter's methylene reactant is not attached to a resin as called for by the claims. Thus, the examiner considers that although Distler does not disclose the claimed methylene reactant attached to a resin, one skilled in the art would have expected that reacting the same with vinylsulfonic acid would result in the claimed Michael adduct. . . . [O]ne desiring to make a sulfoalkylated resin would have found it obvious to do so via a Michael addition reaction such as reaction "(n)" of Distler by selecting a resin substituted methylene reactant.

In other words, the Board concluded that one desiring to make the nonobvious resin resulting from the process recited in claim 8 would know, on the basis of Distler, how to make it. The Board adhered to its decision on reconsideration.

Brouwer appeals, contending that both the examiner and the Board failed to apply the proper test for obviousness established by *Graham v. John Deere Co.* , 383 U.S. 1, 148 USPQ 459 (1966), and its progeny. According to Brouwer, both the examiner and the Board, persuaded that our decision in *In re Durden* , 763 F.2d 1406, 226 USPQ 359 (Fed. Cir. 1985), controlled the outcome of the instant case, failed to weigh the specific differences between the claimed invention -- with *all* its limitations -- and the prior art references, the so-called "second *Graham* factor." See *Graham* , 383 U.S. at 17 ("Under Section 103 . . . differences between the prior art and the claims at issue are to be ascertained [.]"). Specifically, Brouwer contends that the Board erred by treating its disclosure -- namely, the sulfoalkylated resin made according to the process recited in claim 8 -- as prior art, leading it to affirm the examiner's rejection despite the lack of citation to any reference containing a

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suggesting or motivation either (a) to use a resinsubstituted methylene reactant in a generic Michael addition reaction, or (b) to obtain the specific sulfoalkylated resin catalyst made according to the process recited in claim 8. We agree.

The Analysis

The test of obviousness *vel non* is statutory. It requires that one compare the claim's

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"subject matter as a whole" with the prior art "to which said subject matter pertains." 35 U.S.C. Section 103. The inquiry is thus highly fact-specific by design. This is so "whether the invention be a process for making or a process of using, or some other process." *In re Kuehl*, 475 F.2d 658, 665, 177 USPQ 250, 255 (CCPA 1973). When the references cited by the examiner fail to establish a *prima facie* case of obviousness, the rejection is improper and will be overturned. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1986 (Fed. Cir. 1988).

[1] Applying this statutory test to the art of record, we conclude that Brouwer's process invention is not *prima facie* obvious. Although the prior art references the examiner cited teach a generic chemical reaction of a compound containing an active methylene group with an ester of vinylsulfonic acid, we have made clear that "[t]he mere fact that a device or process utilizes a known scientific principle does not alone make that device or process obvious." *Uni royal, Inc. v. Rudkin-Wiley Corp.*, 837 F.2d 1044, 1053, 5 USPQ2d 1434, 1440 (Fed. Cir. 1988). See also *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1462, 221 USPQ 481, 489 (Fed. Cir. 1984) (same). Moreover, the mere possibility that one of the esters or the active methylene group-containing compounds disclosed in Distler could be modified or replaced such that its use would lead to the specific sulfoalkylated resin recited in claim 8 does not make the process recited in claim 8 obvious "unless the prior art suggested the desirability of [such] a modification" or replacement. *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984). Without first knowing Brouwer's claimed process steps or the composition resulting from those steps, there is simply no suggestion in the references cited by the examiner to practice the claimed process. It is therefore not *prima facie* obvious.

[2] The examiner erred by resting his *prima facie* case of obviousness on the purportedly controlling nature of our decision in *Durden* rather than on particularized findings, required by *Graham*, 383 U.S. at 17, regarding a set of one or more references that would make the claimed process obvious, an error the Board failed to correct. As we clearly indicated in *In re Dillon*, a recent in banc decision, "[w]hen any applicant properly presents and argues suitable method claims, they should be examined in light of all . . . relevant factors, free from any presumed controlling effect of *Durden*" or any other precedent. 919 F.2d 688, 695, 16 USPQ2d 1897, 1903 (Fed. Cir. 1990) (in banc), cert. denied, 500 U.S. 904 (1991). See also *In re Ochiai*, 72 F.3d 1565, 1570, 37 USPQ2d 1127, 1132 (Fed. Cir. 1995) ("[T]here are not 'Durden' obviousness rejections' or 'Albertson' obviousness rejections,' but rather only section 103 obviousness rejections."). Having compared Brouwer's claims to the prior art of record, we reverse the rejection of claims 8 through 27 as an incorrect conclusion reached by incorrect methodology.

REVERSED

Footnotes

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Footnote 1. The references are as follows: Distler, *The Chemistry of Vinylsulfonic Acid [I]*, 4 Angew. Chem. Int'l Ed. 300 (1965); and Morrison & Boyd, *Organic Chemistry* 1179-1181 (4th ed. 1983).

Footnote 2. Because Brouwer did not argue the separate patentability of claims 8 through 27 before the Board, all the claims stand (or fall) together. *In re Dillon*, 919 F.2d 688, 692, 16 USPQ2d 1897, 1900 (Fed. Cir. 1990) (in banc), *cert. denied*, 500 U.S. 904 (1991); *In re Kroekel*, 803 F.2d 705, 709, 231 USPQ 640, 642-43 (Fed. Cir. 1986).

Footnote 3. *Michael addition*, named after chemist Arthur Michael (1854-1942), is a standard technique in organic chemistry for reacting a material having an alpha,beta-unsaturated carbonyl group with a material having an active methylene group.

Footnote *. Judge Archer assumed the position of Chief Judge on March 18, 1994.

Footnote **. Honorable James R. Carrigan, United States District Court for the District of Colorado, sitting by designation. Judge Carrigan retired from the federal judiciary effective August 19, 1995, and thus took no part in the disposition of this appeal.

- End of Case -

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In re ROYKA AND MARTIN

(CCPA)

180 USPQ 580

Decided Feb. 7, 1974

No. 9092

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Patentability — Anticipation — Combining references (§ 51.205)

To support anticipation rejection, all elements of claim must be found in reference.

2. Construction of specification and claims — Broad or narrow — In general (§ 22.101)

Construction of specification and claims — By specification and drawings — In general (§ 22.251)

Claims are not read in a vacuum; while they are given broadest reasonable interpretation during prosecution, their terms still must be given meaning called for by specification of which they form a part.

3. Patentability — Anticipation — In general (§ 51.201)

Anticipation requires a finding that claimed invention be disclosed; it is not enough to say that applicants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper.

4. Patentability — Subject matter for patent monopoly — Printed matter (§ 51.611)

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It is not a valid reason for rejection that claim is merely a printed matter variation of design of reference; printed matter may very well constitute structural limitations upon which patentability can be predicated.

Particular patents—Answer System

Royka and Martin, Responsive Answer System, claims 28 and 30 to 36 of application allowed.

Case History and Disposition:**Appeal from Board of Appeals of the Patent Office.**

Application for patent of Stephen F. Royka and Robert G. Martin, Serial No. 648,701, filed June 26, 1967; Patent Office Group 336. From decision rejecting claims 28 and 30 to 36, applicants appeal. Reversed.

Attorneys:

MICHAEL H. SHANAHAN, Fairport, N. Y. (THOMAS M. WEBSTER, Fairport, N. Y., and BORIS HASKELL and PARIS, HASKELL & LEVINE, both of Arlington, Va., of counsel) for appellants.

JOSEPH F. NAKAMURA (FRED W. SHERLING of counsel) for Commissioner of Patents.

Judge:

Before MARKEY, Chief Judge, and RICH, BALDWIN, LANE, and MILLER, Associate Judges.

Opinion Text**Opinion By:**

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of claims 28 and 30-36 of application serial No. 648,701, filed June 26, 1967, entitled "Responsive Answer System." We reverse.

The Invention

The appealed claims are directed to a device in the nature of an answer sheet for use in self-instruction and testing. The answer sheet may be associated with questions or separate therefrom. The essential features of the invention are that there are printed on the answer sheet in "response areas" meaningful information in permanent printing and

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confusing information in printing which can be removed, as by an eraser, both being legible so that a student, seeing a choice of answers to a question, must make a selection. Having made a selection, he then applies an eraser to the selected response area and some of the information will be readily removed. What remains advises him of the correctness or otherwise of his answer. The following figures from the drawings are illustrative:
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Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

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Fig. 1A shows two response areas to a given question before any removing action by the student has taken place and Fig. 1B shows the permanent information remaining in each after erasure of the removable information. Of course, if the student makes an initial choice of area A, showing up "YES" or some other indication of a correct answer, he will not need to proceed further and erase the B area. In a modified form of the invention, a wrong selection, plus erasure, may expose, instead of or in addition to a statement that the answer is wrong, a number or other reference to further material which is to be studied.

A preferred method of printing the permanent meaningful information and the removable confusing information is by that type of xerography in which a fusible toner is used, the permanence of the printing depending on the extent to which the toner image is "fixed" or fused by heat. By successive printings of the two kinds of information with fixing to different degrees, one image can be made permanent and the other made subject to easy removal, both images retaining such similarity of appearance that the user of the answer sheet cannot tell them apart.

Claim 28 is the principal claim, all others being dependent thereon, and reads as follows:

28. A device for selectively indicating information comprising
a support having response areas for presenting information for selection,
permanent printing indicative of meaningful information permanently
fixed to said support within a response area, and
removable printing indicative of confusing information removably fixed to
said support within a response area,
said meaningful and confusing information being substantially legible
even when said permanent and removable printing are fixed over one another on
said support,
said permanent and removable printing being substantially similar such
that an observer cannot determine which information is permanent and which is
removable
whereby the information within a response area is selected by attempting
to remove the printing therein with the failure to remove printing identifying
meaningful information.

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Claims 30-36 add limitations which need not be considered except for noting that claims 33 and 34 alone specify the use of a xerographic toner, for which reason they were rejected on a different ground from the other claims.

The Rejection

The following references were relied on:

Reid et al. (Reid) 356,695 Jan. 25, 1887

Bernstein et al. (Bernstein) 3,055,117 Sep. 25, 1962

Lein et al. (Lein) 3,364,857 Jan. 23, 1968 (filed Feb. 2, 1966)

Claims 28, 30, 31, and 32 were rejected as anticipated under 35 U.S.C. 102 by Bernstein; claims 28, 31, 32, 35, and 36 were rejected as anticipated under § 102 by Reid; and claims 33 and 34 were rejected under 35 U.S.C. 103 for obviousness, on either Bernstein or Reid in view of Lein. These were the examiner's rejections and the board affirmed them, adhering to its decision on reconsideration.

Bernstein discloses an answer sheet in which printed information representing a response is "temporarily concealed from the observer" and he discloses a number of different ways of effectively concealing the response. His specification states:

The objects of the invention are accomplished by utilizing the hiding media to confuse the participant and to render the response and the hiding media indistinguishable and thus conceal the presence, absence, nature or position of the response from the participant. This may be effectuated by careful attention being paid to a number of factors including the design, color and position of the hiding or confusing media.

Fig. 1 of Bernstein's drawings illustrates some of his concealing means:

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The following is the written description:

Referring now to the drawing, FIG. 1 illustrates some of the many optically confusing patterns which may be positioned between the printed structure to be concealed and the point of observation. Column 11 shows the information which is to be concealed. This information is repeated in columns 12 through 16 but in each case is concealed by a pattern in accordance with the present invention. Column 12 utilizes a pattern comprising an alphabetical maze in both line and half tone screen. Column 13 utilizes a pattern comprising an absorbing field having a plurality of irregular dot-like interstices. Column 14 utilizes a pattern comprising a maze of plus signs combined with dots. Columns 15 and 16 illustrate irregular and non-repetitious patterns.

Bernstein says that if at least 50% of the response is actually covered by the opaque portions of the confusion pattern, complete concealment is obtained. He also says that added means of concealment may be used, such as scoring and embossing and perforating the paper in order to scatter the light or let it shine through.

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Reid is entitled "Transformation Picture and Print." The invention is said to be useful for advertisements, Christmas cards, birthday cards, valentines, and the like and as a source of amusement and instruction for children. It consists of a picture or print, part of which is permanently printed and part of which is removable from the paper on which it is printed. For the latter various soluble undercoatings or inks are described. If the picture is washed with a solvent, which may be water, the removable part disappears and the pictorial and/or typographic matter changes. The invention is illustrated by a typical nineteenth century temperance propaganda piece depicting the evils of drink. In the finished picture there are three scenes from left to right: Scene 1, the innocent child leads her father home from the pub; Scene 2, Father sits slumped in the kitchen chair with his bottle beside him, the family wash hanging above his head, this picture being entitled "The Effects of Drink"; Scene 3, Mother stands in front of a sign reading "Pawn Shop." Across the bottom of the picture is a legend which says "Wash the above and see what water will do." Fig. II shows the result of washing with water: Scene 1, a handsome young man and his happy daughter stroll on the street; Scene 2, Father sits erect in a well-appointed room at a cloth-covered table, apparently having a cup of tea, obviously a gentleman; Scene 3, Mother beams from the sideline and the Pawn Shop sign has vanished. Two new subscriptions appear and the words "The" and "Drink" have disappeared, the resultant being a new picture title reading "The Beneficial Effects of Temperance." "The Beneficial" and "Temperance" were covered by some soluble opaque in the original picture. No doubt the overall effect is instruction. Perhaps there was amusement in bringing about the transformation.

Lein relates to xerography and is relied on only for its disclosure of the removability of partially fused toner and the permanence of fully fused toner.

Opinion

[1] As to the § 102 anticipation rejections, it will suffice to consider independent claim 28. If it is not fully met by Reid or Bernstein, neither are the more limited dependent claims. It is elementary that to support an anticipation rejection, all elements of the claim must be found in the reference. We do not find claim 28 anticipated by Bernstein because, as we read the claim, it requires the display of *legible* meaningful and *legible* confusing *information* simultaneously, between which the user of the device may make a selection before he undertakes to remove any of the information from the response area selected by him. The element we find most clearly missing, contrary to the reasoning of the examiner and the board, is the legible confusing *information*. The Patent Office proposes to read this limitation on Bernstein's confusion patterns which are nothing but meaningless obscuring screens, conveying no information and providing the user with no basis for making a *selection*, as called for by claim 28. In appellants' device the legible confusing information—i.e., the wrong answers—are legible in the sense that they can be read as intelligible words, not merely a jumble of type serving to obscure the words of the wrong answers.

Appellants were fully aware of Bernstein and discussed its disclosures in their specification, distinguishing from this and other prior art, saying, in part:

The inventive concept hereof confuses not by physical blocking as taught by the prior art, but by compounding, associating (including disarranging) permanent information with confusing information, usually at least some of which is similar
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in character to the permanent information as to render it impossible to tell which is permanent and which is removable confusing information. In the invention, generally no attempt is made to designedly physically cover the permanent information, but to confuse it beyond interpretation by the presentation of extraneous, removable, confusing information.

[2] Claims are not to be read in a vacuum and while it is true they are to be given the broadest *reasonable* interpretation during

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prosecution, their terms still have to be given the meaning called for by the specification of which they form a part. We cannot read the terms "legible" and "information" on Bernstein's confusion patterns, as did the examiner and the board. They are not "legible," as appellants use the term, and they convey no information.

As to anticipation by Reid, we find neither appellants' basic concept nor the substance of claim 28 to be disclosed. Apparently the solicitor could find little to support the rejection in Reid for all he says in his brief—so far as claim 28 is concerned—is:

Reid discloses a sheet which may be used for instruction and which may have a removable design partly covering a fixed design * * *. Therefore, the disclosure of the reference encompasses the arrangement wherein a removable design covers a fixed design with both designs being substantially legible.

[3] But claim 28 does not call for an arrangement wherein a removable design covers a fixed design. It calls for response areas, which Reid does not have, containing meaningful information in permanent printing together with removable printing conveying confusing information, both legible at the same time, between which a "selection" can be made. The only choice offered to the user by Reid is to follow the instruction to wash the whole visible picture with water or other solvent, thus removing the overprinting, to discover what the permanent picture is. The Patent Office attempt to read claim 28 on this reference is a tour de force. We hold that Reid does not anticipate for failure to meet the limitations of claim 28 to "response areas," to the presentation of two categories of information (meaningful-permanent and removable-confusing) within such areas, and the possibility of selection. Anticipation requires a finding that the claimed invention be disclosed. It is not enough to say that appellants' invention and the reference are both usable for instruction and both consist of permanent and removable printings on paper, as did the solicitor.

The dependent claims rejected with claim 28, as anticipated under § 102, are not anticipated since claim 28 is not anticipated. Some of them merely add features which are disclosed by the references and some do not. Insofar as they do not, they further negative anticipation. The examiner recognized this fact as to claims 33 and 34, which are limited to xerography, and therefore did not reject them under § 102. Similarly, he did not reject claim 30 on Reid or claims 35 and 36 on Bernstein. We find that claims 35 and 36 contain limitations which additionally distinguish from Reid. We have already noted that Reid has no "response areas" as required by claim 28 and so Reid does not disclose the structure of claim 35 which additionally requires both the correct and incorrect answers to appear within the same response area.

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[4] As to claim 36, the examiner said it "is merely a printed matter variation of the design of the reference," Reid. This is not a valid reason for rejection. Printed matter may very well constitute structural limitations upon which patentability can be predicated. We have commented on this matter in *In re Jones*, 54 CCPA 1218, 373 F.2d 1007, 153 USPQ 77 (1967); and *In re Miller*, 57 CCPA 809, 418 F.2d 1392, 164 USPQ 46 (1969), and will not repeat ourselves. The limitations of claim 36 are not remotely suggested by Reid.

There remains the § 103 rejection of claims 33 and 34. Do they, taken together with all of the limitations of claim 28 from which they depend, define obvious subject matter? The difference between claim 28 and these two dependent claims is that they add the limitations to xerography. If Bernstein and Reid showed the claimed invention except for xerography, the addition of the Lein reference would make the subject matter of the claims obvious. But that is not the situation here. Adding the knowledge of xerographic technology to Bernstein or Reid still does not make the invention of claims 33 and 34 obvious for the same reasons we have given above in discussing anticipation. The essence of appellants' invention, as set forth in claim 28, is still missing notwithstanding the addition of the Lein reference and we see nothing in the combinations of references which would have made the invention obvious to one of ordinary skill in the art at the time it was made. We will, therefore, reverse this rejection.

The decision of the board is *reversed*.

- End of Case -

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AT LEAST SOME DEGREE OF PREDICTABILITY IS REQUIRED; APPLICANTS MAY PRESENT EVIDENCE SHOWING THERE WAS NO REASONABLE EXPECTATION OF SUCCESS

Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.).

PREDICTABILITY IS DETERMINED AT THE TIME THE INVENTION WAS MADE

Whether an art is predictable or whether the proposed modification or combination of the prior art has a reasonable expectation of success is determined at the time the invention was made. *Ex parte Erlich*, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986) (Although an earlier case reversed a rejection because of unpredictability in the field of monoclonal antibod-

ies, the court found “in this case at the time this invention was made, one of ordinary skill in the art would have been motivated to produce monoclonal antibodies specific for human fibroblast interferon using the method of [the prior art] with a reasonable expectation of success.” 3 USPQ2d at 1016 (emphasis in original).).

2143.03 All Claim Limitations Must Be Taught or Suggested

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

INDEFINITE LIMITATIONS MUST BE CONSIDERED

A claim limitation which is considered indefinite cannot be disregarded. If a claim is subject to more than one interpretation, at least one of which would render the claim unpatentable over the prior art, the examiner should reject the claim as indefinite under 35 U.S.C. 112, second paragraph (see MPEP § 706.03(d)) and should reject the claim over the prior art based on the interpretation of the claim that renders the prior art applicable. *Ex parte Ionescu*, 222 USPQ 537 (Bd. Pat. App. & Inter. 1984) (Claims on appeal were rejected on indefiniteness grounds only; the rejection was reversed and the case remanded to the examiner for consideration of pertinent prior art.). Compare *In re Wilson*, 424 F.2d 1382, 165 USPQ 494 (CCPA 1970) (if no reasonably definite meaning can be ascribed to certain claim language, the claim is indefinite, not obvious) and *In re Steele*, 305 F.2d 859, 134 USPQ 292 (CCPA 1962) (it is improper to rely on speculative assumptions regarding the meaning of a claim and then base a rejection under 35 U.S.C. 103 on these assumptions).

LIMITATIONS WHICH DO NOT FIND SUPPORT IN THE ORIGINAL SPECIFICATION MUST BE CONSIDERED

When evaluating claims for obviousness under 35 U.S.C. 103, all the limitations of the claims must be considered and given weight, including limitations which do not find support in the specification as originally filed (i.e., new matter). *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983) *aff'd mem.* 738 F.2d 453 (Fed. Cir. 1984) (Claim to a catalyst expressly excluded the presence of sulfur, halogen, uranium, and a combination of vanadium and phosphorous. Although the negative limitations excluding these elements did not appear in the specification as filed, it was error to disregard these limitations when determining whether the claimed invention would have been obvious in view of the prior art.).

2144 Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103

RATIONALE MAY BE IN A REFERENCE, OR REASONED FROM COMMON KNOWLEDGE IN THE ART, SCIENTIFIC PRINCIPLES, ART-RECOGNIZED EQUIVALENTS, OR LEGAL PRECEDENT

The rationale to modify or combine the prior art does not have to be expressly stated in the prior art; the rationale may be expressly or impliedly contained in the prior art or it may be reasoned from knowledge generally available to one of ordinary skill in the art, established scientific principles, or legal precedent established by prior case law. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). See also *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (setting forth test for implicit teachings); *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990) (discussion of reliance on legal precedent); *In re Nilssen*, 851 F.2d 1401, 1403, 7 USPQ2d 1500, 1502 (Fed. Cir. 1988) (references do not have to explicitly suggest combining teachings); *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985) (examiner must present convincing line of reasoning supporting rejection); and *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993) (reliance on logic and sound scientific reasoning).

THE EXPECTATION OF SOME ADVANTAGE IS THE STRONGEST RATIONALE FOR COMBINING REFERENCES

The strongest rationale for combining references is a recognition, expressly or impliedly in the prior art or drawn from a convincing line of reasoning based on established scientific principles or legal precedent, that some advantage or expected beneficial result would have been produced by their combination. *In re Sernaker*, 702 F.2d 989, 994-95, 217 USPQ 1, 5-6 (Fed. Cir. 1983).

LEGAL PRECEDENT CAN PROVIDE THE RATIONALE SUPPORTING OBVIOUSNESS ONLY IF THE FACTS IN THE CASE ARE SUFFICIENTLY SIMILAR TO THOSE IN THE APPLICATION

The examiner must apply the law consistently to each application after considering all the relevant facts. If the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection. "The value of the exceedingly large body of precedent wherein our predecessor courts and this court have applied the law of obviousness to particular facts, is that there has been built a wide spectrum of illustrations and accompanying reasoning, that have been melded into a fairly consistent application of law to a great variety of facts." *In re Eli Lilly & Co.*, 902 F.2d 943, 14 USPQ2d 1741 (Fed. Cir. 1990).

RATIONALE DIFFERENT FROM APPLICANT'S IS PERMISSIBLE

The reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), *cert. denied*, 500 U.S. 904 (1991) (discussed below). Although *Ex parte Levengood*, 28 USPQ2d

In re SOLI

(CCPA)

137 USPQ 797

Decided June 6, 1963

Appl. No. 6999

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Court of Customs and Patent Appeals--Briefs (§ 28.05)

Wherever possible, issues should be crystallized before appeal to Court of Customs and Patent Appeals; it is neither the function of oral argument or briefs before court to question for the first time the propriety of actions of examiner or Board to which a response conveniently could have been made before Patent Office.

2. Evidence--Judicial notice (§ 36.20)

Court takes judicial notice of use of "controls" in various experimental procedures.

3. Pleading and practice in Patent Office--Rejections (§ 54.7)

When Patent Office finds, in words of 35 U.S.C. 103, "differences between the subject matter sought to be patented and the prior art," it may not, without basis in logic or scientific principle, merely allege that such differences are either obvious or of no patentable significance and thereby force applicant to prove conclusively that it is wrong; such is not the rule relating to burden of proof in Court of Customs and Patent Appeals; what proof applicant must offer to overcome position of Office supporting rejection can be determined only on basis of facts in any particular case.

Particular patents--Prospecting

Soli, Petroleum and Natural Gas Prospecting, claim 13 of application refused.

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Case History and Disposition:

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Appeal from Board of Appeals of the Patent Office.

Application for patent of Giorgio G. Soli, Serial No. 587,521, filed May 28, 1956; Patent Office Division 63. From decision rejecting claim 13, applicant appeals. Affirmed.

Attorneys:

CONDER C. HENRY, Washington, D.C., for appellant.

CLARENCE W. MOORE (RAYMOND E. MARTIN of counsel) for Commissioner of Patents.

Judge:

Before WORLEY, Chief Judge, and RICH, MARTIN, SMITH, and ALMOND, Associate Judges.

Opinion Text**Opinion By:**

RICH, Judge.

This appeal is from the decision of the Patent Office Board of Appeals affirming the examiner's rejection of method claim 13, the sole claim in application Ser. No. 587,521, filed May 28, 1956, for "Petroleum and Natural Gas Prospecting."

The basis for and the general nature of appellant's invention is disclosed in the specification as follows:

The method is based on the fact that, in many instances in oil and gas areas, gaseous hydrocarbons are slowly escaping through the sedimentary formations to the surface. These gases serve as a steady supply of carbon and energy to hydrocarbon-oxidizing bacteria, resulting in the intensive multiplication of these micro-organisms.

The present invention is directed to a method of determining the presence and relative amounts of hydrocarbon-oxidizing bacteria in the soil, these bacteria being an indication of the presence of petroleum hydrocarbons. A feature of the invention is utilization of the ability of hydrocarbon-oxidizing bacteria to grow and produce turbidity [i.e., a murky or muddied condition] in a liquid mineral culture medium in which a hydrocarbon gas is dissolved.

Claim 13 reads as follows (the breakdown being ours):

13. A method of prospecting for subterranean hydrocarbon deposits

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comprising the steps of

[1] collecting samples of soil at various depths in certain locations in a prospective area,

[2] incubating at least one culture of each of said soil samples in a mineral nutrient liquid medium in the presence of an atmosphere of methane,

[3] simultaneously incubating at least another of said cultures of each of the same soil sample in a mineral nutrient liquid medium in the presence of an atmosphere of propane,

[4] simultaneously incubating an additional culture of said same soil sample in a mineral nutrient liquid medium in the presence of atmospheric air,

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[5] determining the amount of hydrocarbon-oxidizing bacteria in said cultures by

(a) a measurement of the amount of turbidity of said nutrient medium caused by the growth of said bacteria exposed to said methane and propane atmospheres, and

(b) using said culture incubated in the presence of atmospheric air as a control for said first-mentioned cultures,

[6] the ratio of soil to culture medium being kept to a minimum.

The Patent Office has rejected this claim as unpatentable over the combined teachings of the following references:

Taggart 2,349,472 May 23, 1944

Strawinski 2,665,237 Jan. 5, 1954

Porter, *Bacterial Chemistry and Physiology*, John Wiley & Sons, Inc., 1946, page 95.

Both Taggart and Strawinski disclose methods of prospecting for subterranean hydrocarbon deposits which include collecting samples of soil at various depths in certain locations in a prospective area and thereafter employing various means to analyze the amount of and/or kind of hydrocarbon-oxidizing bacteria in such samples. The pertinence of the Porter reference will be discussed later.

Appellant's several arguments as to why the references of record would not render his invention obvious to one skilled in the art will be considered as they relate to the above-designated sections of his claim.

Section [1]: Soil Sampling Depth.

Appellant argues in his brief

Particular attention is given [in appellant's invention] to the depth of sampling in relation to the amount of organic matter in the soil, since appreciable amount of such organic matter could unfavorably affect the final results. The amount of organic matter decreases with depth; therefore, the deeper the samples within certain limits, the more reliable the results. Decomposition of organic matter in

the first layers of soil could give rise to methane gas, which would support methane-oxidizing bacteria, which, in turn, would furnish false positive results as far as the presence of oil and gas at greater depths is concerned. For this reason alone, it is submitted, appellant's claim is patentable over Taggart [sic], who specifies 6 inches of surface soil, and Strawinski, who also specifies surface soil at a slightly greater depth. [Strawinski designates this depth as "below six inches, preferably at depths of 24" or more."]

It is clear that the disclosure in appellant's specification does not make soil-sampling depth critical. At one portion thereof it states that soil samples should be taken "at a depth not less than 6 feet." Another portion thereof states, however, merely that soil samples should be collected "at a depth where organic matter is reduced to a minimum." In view of these facts and additionally in view of the fact that we can see no distinction of substance between a depth of soil sampling which may be less than 6 feet and one, as disclosed in Strawinski, which may be two feet "or more" we are not persuaded, by appellant's argument that we should "interpret" the claim in the light of his specification disclosure, that even such an "interpretation" would distinguish the claim from the prior art. All the claim contains by way of limitation is "various depths." It appears to include depths of the prior art.

Sections [2] and [3]: *Simultaneously Incubating in Different Atmospheres Portions of the Same Soil Sample in a Liquid Medium.*

Appellant's specification discusses this aspect of his invention as follows:

* * * this invention is directed to the simultaneous isolation of bacteria able to use methane and to bacteria which attack ethane or propane but which may not be able to use methane. Since we know that neither ethane nor propane are commonly found in soil as a result of decomposition of organic matter, the separate use of methane and propane (or ethane) as test gasses on the same soil sample is an important part of this invention.

To this end appellant places a measured amount of a liquid "culture medium" into five vials.¹ These vials are then "innoculated" with measured amounts of soil. Two of the vials are then filled with methane, two with propane. The contents of the fifth vial will be discussed,

Page 799

infra. The vials are then incubated for two weeks at a temperature of approximately 28° to 30°C.

As to the reason why methane and propane atmospheres should not be mixed, the specification says:

If growths occurred only in the cultures incubated under an atmosphere of methane, the results for these particular soil samples are held as questionable, for the presence of bacteria able only to oxidize methane, cannot be taken as a positive indication of petroleum hydrocarbons for reasons explained above. If bacterial growth occurred both in methane and propane-exposed cultures, then the results are recorded as positive.²

The relationship between the above portions of appellant's disclosure and the relevant

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portions of the Taggart and Strawinski references can readily be seen from the following analysis thereof made by the board:

Taggart takes samples of soil from spaced points in the area under investigation, and places each sample in a sealed chamber containing a hydrocarbon gas and oxygen. The samples are allowed to stand for a previously selected period of time. Taggart found that when a sample contains substantial amounts of hydrocarbon-consuming bacteria a pressure drop occurs in the atmosphere above the sample. A manometer attached to the chamber containing the sample is read periodically and the drops in the pressure are recorded. * * *.

Strawinski is asserted to be an improvement on the Taggart method.

Strawinski collects samples from the area under investigation in the same general manner as Taggart. Each sample is thoroughly mixed with a nutrient medium and about 50 ml of the mixture is placed in a reactor vessel. A gas mixture preferably composed of carbon dioxide, oxygen or air and methane at substantially atmospheric pressure is then admitted to the reactor vessel and the latter is connected by a siphone arrangement to a reservoir under atmospheric pressure containing the same nutrient medium that was mixed with the soil sample. The reactor vessel contents are then allowed to undergo incubation at a temperature of 25 to 35°C. After standing for some time it is observed that some of the nutrient medium has passed from the reservoir into the reactor vessel by reason of consumption of gas in the latter vessel by the microorganisms in the soil sample. This transfer of nutrient medium from the reservoir to the reactor is permitted to continue until an arbitrarily selected liquid level is reached in the reactor vessel. The patentee states that a liquid level corresponding to a volume of 100 ml is sufficient to indicate with sufficient accuracy completion of the reaction of the microorganisms on the hydrocarbon. Strawinski therefore measures the time which elapses for the level of liquid in the reactor to reach the 100 ml mark, and this time is an indication of the activity of the microorganisms in the sample.

We also note with respect to Taggart that he discloses--

* * * that the general principle involved in the present invention can be utilized without following the specific procedure outlined above. * * *. Another refinement is to divide each sample into portions and subject one portion to the action of methane, while another portion is subjected to the action of heavier hydrocarbons under the same conditions, the same concentration of hydrocarbons being used in each case. This procedure serves to eliminate errors which might arise by reason of the fact that the soil may contain bacteria which have a preferential action on methane.

We think it unquestionably clear that Taggart discloses appellant's contemplated *simultaneous* incubation, in *different* hydrocarbon atmospheres, of portions of the same soil sample. We consider unimportant the fact that Taggart does not employ in these incubations a liquid nutrient medium inasmuch as Strawinski clearly discloses that the art had recognized the existence of uncontrollable "variables" which would be encountered in attempting an incubation of hydrocarbon-oxidizing bacteria in the absence of such a medium. In this regard Strawinski states:

* * * such variables are eliminated by the use of a relatively large amount

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of [liquid] nutrient which amount

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compared to any moisture content of the sample and any nutrient content is so large that any variations in moisture or nutrient content are substantially "ironed out" and each sample virtually standardized.

Sections 4 and 5(b): Incubating in Atmospheric Air Another Portion of the Same Soil Sample in a Liquid Medium and Using This Incubation as a "Control."

The contents of appellant's previously noted fifth vial differs from those of his others only in that atmospheric air is used therein rather than a hydrocarbon gas. The reason for this additional vial is disclosed as follows:

If the soil samples were taken in the described manner, no [bacterial] growth will occur in the culture incubated under atmospheric air, as the hydrocarbon-oxidizing bacteria eventually present will not develop due to the absence of a carbon source. This serves as a control to ascertain that the eventual bacteria growths in the hydrocarbon-exposed cultures are not due to a carbon source other than the hydrocarbon.

The Patent Office position relating to the patentable significance of a control was set forth by the examiner. He said:

Applicant states that Taggart has no such control like applicant's. There is no issue taken with this view, but when one is attempting to determine the number of bacterial cells that have come to be since a certain time lapse, how can that determination possibly be made without a control? Such a control is standard procedure throughout the entire field of bacteriology.³

The solicitor notes that this statement by the examiner is "unchallenged." Appellant responds by asking whether he must deny all allegations of the examiner before he can appeal.

[1][2] This court has long held that wherever possible, issues should be crystallized *before* appeal to this court. It is neither the function of oral arguments nor briefs before this court to question for the first time the propriety of actions of the examiner or the board to which a response conveniently could have been made before the Patent Office. See *In re Chevenard*, 31 CCPA 802, 139 F.2d 711, 60 USPQ 239. This is not a case where the examiner's allegation appears to be based on mere conjecture. On the contrary, this court takes judicial notice of the use of "controls" in various experimental procedures.⁴ Even if we were to assume, *arguendo*, that the rule of this court were not as stated in the Chevenard case, we note that appellant's attempt to refute what we think is the justifiable position of the Patent Office relating to the *skill of the art* consists merely of stressing what the Patent Office has admitted--that neither Strawinski nor Taggart discloses, by itself, the use of a control. On the question before us, we think that fact is not significant. It is well within ordinary skill of the art to use a control.

Section 5(a): Determining the Amount of Hydrocarbon-Oxidizing Bacteria in the Cultures by Measuring the Turbidity of the Nutrient Medium.

Appellant's disclosure in this regard states:

The degree of turbidity in each of the four hydrocarbon-incubated cultures is * * *

measured by means of a colorimeter-spectro-photometer, * * * and the average turbidity from the four cultures [other than that using air as an atmosphere] for each soil sample calculated on the basis of transmission readings.

In discussing the pertinence of the reference disclosures on this point, appellant states: "Admittedly, the measurement of turbidity of a bacterial culture as an index of the number of bacteria present, is an old process. It is disclosed by Porter." He argues, however, that when his method is "viewed in its entirety" it may not properly be said that he has merely substituted Porter's method of estimating the number of bacteria present for either Taggart's or Strawinski's pressure-drop method. We do not agree. Appellant's argument seems to be predicated, at least in part, on the idea that his bacterial measurement is somehow more "direct" than that of either Taggart or Strawinski. We see no distinction, insofar as directness of measurement of bacterial growth is concerned, between the bacterial measurement method used by either Taggart or Strawinski on the one hand and that

Page 801

used by Porter and appellant on the other. Porter actually refers to the "*Opacity Method*" for "the enumeration of bacteria" as being an "indirect" method. Whatever doubt we might have on this point we would resolve against appellant in view of Strawinski's disclosure that a "spectrophotometer," while "not essential" in his process, may be used "to determine the actual amount of hydrocarbon consumed in milliliters." We feel that one skilled in the art, knowing from Strawinski that a photometric measurement had been used for one purpose in the gas and oil prospecting art, if wishing to improve the method of enumerating bacteria in a process utilizing a light-transmitting liquid culture medium, would be expected to turn to other references dealing with photometric measurements, similar to Porter, to see what other possible utilization could be made of such an *indirect* measuring means.

Section 6: *The Ratio of Soil to Culture Medium Being Kept to a Minimum.*

The board in discussing appellant's arguments relating to this section of the claim said:

Appellant emphasizes that he keeps the ratio of soil to culture medium at a minimum. We are constrained to agree with the examiner that this appears to be no more than conventional procedure in bacteriological experiments. Further, it appears to us that Strawinski would have a large excess of culture medium relative to soil.

We have not been persuaded by appellant that this position of the Patent Office "is unsound." As the solicitor would say, the board's allegation with respect to Strawinski is "unchallenged" even on appeal to this court. Furthermore, we see in appellant's specification in this regard merely a statement that a certain ratio of soil to culture medium "is the most satisfactory." No statement is contained therein that would give any basis to appellant's contention that a particular ratio is critical, nor, for that matter, what this ratio may be inasmuch as it is referred to merely as a "minimum."

[3] When, as in the instant case, the Patent Office finds, in the words of 35 U.S.C. 103, "differences between the subject matter sought to be patented and the prior art," it

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may not, without some basis in logic or scientific principle, merely allege that such differences are either obvious or of no patentable significance and thereby force an appellant to prove conclusively that it is wrong. Such is not and never has been the rule relating to burden of proof in this court. What proof an applicant must offer to overcome a position of the Patent Office supporting a rejection can be determined only on the basis of the facts in any particular case. In the instant case, however, the office position relating to the alleged obviousness of the differences which exist between the claimed invention and the prior art seems to us to be founded both on logic and sound scientific principle. We find that appellant failed to rebut this position.

The decision of the board is *affirmed*.

Footnotes

Footnote 1. In discussing the culture medium appellant's specification says:

The composition of the culture medium needs also particular attention, especially in the method described herein as the method itself relies for its diagnostic aims on the presence or absence of bacterial growth. The medium, therefore, should be such as to promote the growth of hydrocarbon-oxidizing bacteria and discourage the growth of other micro-organisms.

Inasmuch, however, as claim 13 does not state the composition of this medium, we will not consider further the particular composition of appellant's liquid culture medium.

Footnote 2. Appellant's reference to "recorded" results is directed to the fact that after the degree of turbidity of the vial cultures is determined and the results labeled as positive or questionable, these results are placed on a map of the area from which the soil samples were taken, next to the particular soil sample to which the results relate. Lines are drawn on this map connecting the points of soil sampling where the soil contains equal amounts of hydrocarbon-oxidizing bacteria as determined by the method of the appealed claim. A similar mapping of test results is disclosed by Strawinski.

Footnote 3. The Porter reference, while not cited by the Patent Office for this reason, would seem to support the examiner's position. It states:

Indirect Count. Several methods have been proposed for the enumeration of bacteria by indirect methods.

1. The Opacity Method. The opacity of the bacterial suspension to be estimated by this method is *compared with a control suspension of standard opacity*, such as a barium sulfate solution or a bacterial suspension which has been previously counted. [Last emphasis ours.]

Footnote 4. One need not stir from the TV to discover that "control" groups are used in such everyday occurrences as the testing of the efficacy of toothpaste.

- End of Case -

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In re Grose and Flanigen

(CCPA)

201 USPQ 57

Decided Jan. 18, 1979

No. 78-573

U.S. Court of Customs and Patent Appeals

Headnotes

PATENTS

1. Board of Appeals -- Issues determined (§ 19.30)

Court of Customs and Patent Appeals -- Issues determined (§ 28.20)

Patentability -- Anticipation -- In general (§ 51.201)

Patentability -- Invention -- In general (§ 51.501)

Anticipation is ultimate in obviousness, so that Board of Appeals' affirmance of obviousness rejection encompasses question of whether applicant's material is different from reference.

2. Court of Customs and Patent Appeals -- Jurisdiction (§ 28.05)

Court of Customs and Patent Appeals reviews decisions, not reasoning, of Board of Appeals.

3. Patentability -- Composition of matter (§ 51.30)

Ultimate question in ascertaining whether particular zeolite is different species from those of like chemical composition is whether it has same crystal structure.

4. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)**

Ultimate identification of different crystal structures in zeolite art resides in X-ray diffraction pattern, although other evidence directed to diffraction data itself, such as testimony that difference in data between applicant's and reference's zeolites greatly exceed magnitude of expected variations in data, and comparative data obtained on same apparatus under same conditions, is not necessarily secondary.

5. Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)

No reason exists for applying law relating to structural obviousness of compounds that are homologs or isomers of each other to case involving zeolites.

6. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- In general (§ 51.501)**

When Patent and Trademark Office seeks to rely upon chemical theory, in establishing prima facie case of obviousness, it must provide evidentiary support for existence and meaning of that theory.

7. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)**

Indicated zeolites are not compounds that are homologs or isomers of another, but are mixtures of various compounds related to each other by particular crystal structure.

8. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)**

One assumption underlying prima facie obviousness rejection based upon structural relationship between compounds, such as adjacent homologs, is that method disclosed for producing one would provide those skilled in art with method for producing other, so that rejection of argument that prior art discloses no method for obtaining claimed zeolite on ground that claims were drawn to composition, was incorrect.

9. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)**

Determining whether chemical composition is prima facie obvious from another may rest on whether differences in structure and properties of compositions can be accounted for by obvious modifications in synthesis process or by obvious modifications of one composition to yield other.

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10. Patentability -- Composition of matter (§ 51.30)

Though nonobviousness of particular process for preparing claimed composition would not be determinative of nonobviousness of composition, a holding that composition would have been nonobviousness would require that prior art fail to disclose or render obvious process for preparing it; if prior art of record fails to disclose or render obvious method for making claimed compound, at time invention was made, it may not be legally concluded that compound itself was in possession of public.

11. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)**

Failure of prior art to disclose or render obvious method for making any composition of matter, whether compound or mixture of compounds, precludes conclusion that composition would have been obvious.

12. Patentability -- Composition of matter (§ 51.30)**Patentability -- Invention -- Specific cases -- Chemical (§ 51.5093)**

Other factors that must be given weight in determining whether subject matter as whole would have been obvious are whether prior art suggests particular structure or form of composition as well as suitable methods of obtaining structure or form.

Particular patents -- Aluminosilicate

Grose and Flanigen, Crystalline Aluminosilicate and Process for Preparing Same, rejection of claims 1-2 affirmed.

Case History and Disposition:

**Appeal from Patent and Trademark Office Board of Appeals.
Application for patent of Robert W. Grose and Edith Marie
Flanigen, Serial No. 432,137, filed Jan. 10, 1974. From decision rejecting
claims 1-2, applicants appeal. Affirmed.**

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Attorneys:

**Richard G. Miller, New York, N.Y. (James C. Arvantes, Arlington,
Va., of counsel) for appellants.**

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**Joseph F. Nakamura (Gerald H. Bjorge, of counsel) for
Commissioner of Patents and Trademarks.**

Judge:

Before Markey, Chief Judge, and Rich, Baldwin, Lane, and Miller, Associate Judges.

Opinion Text

Opinion By:

Markey, Chief Judge.

Appeal from the decision of the Patent and Trademark Office (PTO) Board of Appeals (board) sustaining the rejection under 35 USC 103 of claims 1-2 of application serial No. 432,137, filed January 10, 1974, for "Crystalline Aluminosilicate and Process for Preparing Same." We affirm.

The Invention

The invention is directed to a synthetic crystalline aluminosilicate of the molecular sieve or zeolitic type, named "zeolite Upsilon" by appellants. Claims 1 and 2 read:

1. A synthetic crystalline zeolitic molecular sieve having a composition expressed in terms of mole ratios of oxides as follows:¹

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

$0.9 \pm 0.1 M \text{ n } 2\text{O} : \text{Al}_2\text{O}_3 : 2.4 - 3.4 \text{ SiO}_2 : 0.4 - 4.5 \text{ H}_2\text{O}, ??$

wherein "M" is at least one or a mixture of two or more of hydrogen, ammonium or metal cations having a valence of "n", said zeolitic molecular sieve in its sodium cation form having an X-ray powder diffraction pattern containing at least those d-spacings set forth in Table B.

2. Composition according to claim 1 wherein "M" represents the sodium cation.

Table B is disclosed in the specification:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Table B represents an abbreviated version of the X-ray powder diffraction pattern used by appellants to identify their zeolite Upsilon and distinguish it from other zeolites. A more detailed X-ray diffraction pattern is disclosed in Table A of the specification:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Measurement of the X-ray powder diffraction pattern is described as follows:

Standard techniques were employed to obtain the foregoing data. The radiation was the K-alpha doublet of copper, and a Geiger-counter spectrometer with a strip-chart pen recorder was used. The peak heights, I and the positions as a

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function of 2 times theta (ν), where theta is the Bragg angle, were read from the spectrometer chart. From these the relative intensities, $100 I/I_0$, where I_0 is the intensity of the strongest line or peak, and $d(\text{obs.})$, the interplanar spacing in Angstrom units corresponding to the recorded lines were calculated. The particular x-ray technique and/or apparatus employed, the humidity, the temperature, the orientation of the powder crystals and other variables, all of which are well known and understood by those skilled in the art of x-ray crystallography or diffraction, can cause some variation in the intensities and positions of the x-ray lines.

Appellants disclose that zeolite Upsilon is prepared by hydrothermal crystallization from a gel with the following mole ratios of oxides:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

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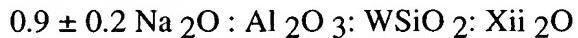
Crystallization is conducted by heating the gel, at 100°C and atmospheric pressure, until the crystalline product has been obtained. The presence of chromium or iron oxides, in addition to the above reactants, is disclosed as essential to obtaining zeolite Upsilon as the major zeolite product.² After crystallization, the zeolite crystals are separated by filtration, washed with distilled water until the pH of the effluent is between 9 and 12, and dried at 110°C.

Zeolite Upsilon is disclosed as being useful as a desiccant, particularly in drying hydrocarbon gas streams and air streams to be fractionated in the liquid state, and as an adsorbent for carbon dioxide.

The Rejection

Claims 1 and 2 were rejected under 35 USC 102 or at least 35 USC 103 as unpatentable over the single reference patent to Milton, No. 3,030,181, dated April 17, 1962.

Milton discloses a synthetic crystalline aluminosilicate, called zeolite R, with the following chemical formula:



wherein W - 3.45 - 3.65 and X - 7 when fully hydrated.

Milton's zeolite R has an X-ray powder diffraction pattern substantially like that shown in this table:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Milton's crystallization process for preparing zeolite R may use a reactant mixture with these mole ratios of oxides:

Table set at this point is not available. See table in hard copy or call BNA PLUS at 1-

800-452-7773 or 202-452-4323.

The process conditions are essentially the same as those described by appellants, except that Milton makes no reference to the presence of iron or chromium oxides in the reaction mixture.

The examiner viewed the chemical composition of the claimed zeolite as encompassed by that of Milton's zeoliteR. The only arguable chemical difference between the two zeolites, i.e., Milton's minimum SiO₂/Al₂O₃ ratio of 3.45 as compared to appellants' maximum SiO₂/Al₂O₃ ratio of 3.4, was not found to be a significant distinguishing feature because "the claimed numerical value of '3.4' which is not limited as to the digit in the second decimal place reads on or encompasses Milton's numerical value of '3.45'."

The examiner found the differences between appellants' 12 X-ray diffraction d-spacings and those reported for Milton's zeolite R insufficient to establish that the claimed zeolite has a different crystal structure from zeolite R because, inter alia, X-ray diffraction data for a given zeolite can vary depending on variable factors. Appellants were invited to submit expert testimony under 37 CFR 1.132, explaining why the d-spacings recited in the claims define a crystal structure different from that of Milton, but no such testimony was submitted.

The Board

The board essentially agreed with the examiner that appellants' and Milton's zeolites are "the same chemically." After analyzing the maximum SiO₂/Al₂O₃ ratio of 3.4 in the instant claims and Milton's minimum ratio of 3.45 from the standpoint of significant digits, the board concluded that "the differences, if any, are de minimis and of no significance."

In comparing appellants' and Milton's d-spacings, the board found substantial differences in their values and relative intensity.³ Concluding therefrom that the zeolites are different materials, the board reversed the rejection under 35 USC 102.

In addressing the question of obviousness, the board noted that the claimed zeolite had been disclosed as useful for only the purposes known in the art for zeolites in general, that no unexpected advantages were evident, and that the only distinguishing

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feature of the claimed zeolite, i.e., the different diffraction pattern, had not been shown to be useful in any manner. Thus, the board affirmed the 35 USC 103 rejection, saying:

The new zeolites are certainly closely related to known zeolites, being chemically identical, and the properties of the new zeolite must be considered in determining its patentability, as in the case of closely related chemical compounds (homologs, isomers, analogs). See *In re Papesch*, 315 F.2d 381, 137 USPQ 43 . Accordingly, consistent with past decisions, we will allow claims to new and unobvious forms which exhibit a significant change in properties, but we will refuse claims to mere novel forms which do not possess significantly different properties. The present case falls in the latter category.

In requesting reconsideration, appellants repeated their argument that the claimed

zeolites are not prepared by modifying Milton's zeolite but rather by a unique process, requiring the presence of Fe₂O₃ or Cr₂O₃ in the reactant mixture, and that nothing of record suggests or renders obvious this unique process. In response, the board dismissed the arguments as pertaining to the process for making the zeolites, while the claims are drawn not to the process but to the composition itself.

Issue

The issue is whether the zeolite of claims 1 and 2 would have been obvious to one of ordinary skill in the zeolite art in view of Milton.

Opinion

[1][2]The board concluded that appellants' zeolite, because it is a different material from Milton's zeolite R, was not anticipated, and therefore reversed the §102 rejection, citing *In re Arkley*, 59 CCPA 804, 455 F.2d 586, 172 USPQ 524 (1972), and *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The board's affirmation of the rejection for obviousness under §103 encompasses the question of whether appellants' and Milton's zeolites are different materials, however, because anticipation is the ultimate in obviousness. See *In re Pearson*, 494 F.2d 1399, 1402, 181 USPQ 641, 644 (CCPA 1974); *In re Kalm*, 54 CCPA 1466, 1470, 378 F.2d 959, 962, 154 USPQ 10, 12 (1967). We review the decision, not the reasoning, of the board. If the record fails to establish a significant difference in the involved zeolites, the board's decision upholding the §103 rejection must be affirmed.⁴

The claims define appellants' synthetic zeolite in terms of its chemical composition and in terms of its physical, i.e., crystal, structure. We agree with the board's conclusion that the claimed zeolite and Milton's zeolite R have the same chemical composition, and with the board's analysis in support thereof. Hence discussion of the alleged difference in SiO₂/Al₂O₃molar ratios is unnecessary. The significance of differences in X-ray diffraction data, however, does require consideration.

Appellants have followed the apparently universal practice in this art of "fingerprinting" the crystal structure of their zeolite through a characteristic X-ray powder diffraction pattern. Thus, the first question is whether the pattern recited in appellants' claims defines a crystal structure different from that of Milton.

Comparison of Table B of appellants' claims with Table I of Milton establishes that the X-ray diffraction patterns are very similar. The differences in the values and relative intensities of the d-spacings⁵ caused the board to conclude that the two zeolites are different materials. On the present record we disagree with that conclusion of the board.

[3]X-ray powder diffraction data are merely an analytical tool for identifying polycrystalline materials according to differences in crystal structure.⁶ The ultimate question, in ascertaining whether a particular zeolite is a different species from those of like chemical composition, is

whether it has the same crystal structure. Appellants are claiming a crystal structure. Thus, we are concerned not with whether there are differences in d-spacing values and relative intensities, but with whether such differences support a conclusion that

appellants' and Milton's zeolites have different crystal structures.

Appellants disclosed in their specification, as well known to those skilled in X-ray crystallography, that the apparatus used, the humidity, temperature, orientation of the powder sample, and other variables, can cause variations in the values and relative intensities of d-spacings. Appellants' specification does not, however, disclose the expected magnitude of such variations.

An indication of the possible magnitude of such variations can be found in an earlier Milton patent, also of record, No. 3,010,789, dated November 28, 1961, which states:

The relative intensities and the positions of the X-ray lines are only slightly different for the various, ion-exchanged forms of zeolite H.⁷ The patterns show substantially all of the same lines, and all meet the requirements of a unit cell of approximately the same size, indicating that the spatial arrangement of silicon, oxygen and aluminum atoms, i.e., the arrangement of the AlO₄ and SiO₄tetrahedra, are essentially identical in all forms of zeolite H. The appearance of a few minor lines, and the disappearance of others, from one form of zeolite H to another, as well as slight changes in intensities and positions of some of the X-ray lines, may be attributed to the different sizes and numbers of exchangeable cations present in the various forms of the zeolite.

The differences in diffraction data disclosed for the various forms of zeolite H are as great as, and in some respects are greater than, the differences between appellants' claimed zeolite and Milton's zeoliteR.

Differences between appellants' zeolite and Milton's zeolite R cannot be attributed to a difference in cation form, because the diffraction data for both are those of the fully cationized sodium cation form.

The specification of the Milton 789 patent also speaks, in language similar to that in appellants' specification, of variations in diffraction data to be expected from other sources:

The particular X-ray technique and/or apparatus employed, the humidity, the temperature, the orientation of the powder crystals, and other variables, all of which are well known and understood to those skilled in the art of X-ray crystallography or diffraction, may also

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cause some variations in the intensities and positions of the X-ray lines. Thus, the X-ray data given herein to identify zeolite H are not to exclude those materials which, due to some variable mentioned above or otherwise known to those skilled in the art, fail to show all of the tabulated X-ray lines, or show a few extra ones that are permissible to the crystal system of the zeolite, or show a slight change in intensity or shift in position of some of the X-ray lines.

The present record does not support the conclusion that appellants' zeolite and Milton's zeolite R are zeolites having different crystal structures. The admitted permissible variations in the diffraction data of appellants' zeolite would embrace, at least *prima facie*, the diffraction data disclosed for Milton's zeoliteR. Thus, this is not a situation where the difference in diffraction pattern could only be attributed to a Copyright 2005, The Bureau of National Affairs, Inc. Reproduction or redistribution, in whole or in part, and in any form, without express written permission, is prohibited except as permitted by the BNA Copyright Policy. <http://www.bna.com/corp/index.html#V>

difference in crystal structure.

[4]The *prima facie* case stands unrebutted, appellants having declined the examiner's invitation to submit expert testimony. Appellants assert in their reply brief that "the ultimate proof of a zeolite's identity resides in its X-ray diffraction pattern," and that "all other evidence, including expert testimony, can only be secondary, i.e., a rationalization of the X-ray data." Appellants are correct in stating that ultimate identification of different crystal structures in this art resides in the X-ray diffraction pattern. They incorrectly evaluate the potential significance of evidence directed to the diffraction data itself, such as testimony that the difference in data between appellants' and Milton's zeolites greatly exceeds the magnitude of expected variations in data, and comparative data obtained on the same apparatus under the same conditions.

Though the board's decision must be affirmed, its reasoning with respect to obviousness considerations was incorrect. The board's basis for finding *prima facie* obviousness was that the involved zeolites were "closely related" in much the same manner that homologs are closely related, i.e., they are structurally obvious one from the other. Citing *In re Papesch*, *supra*, the board concluded that the claimed zeolite was not patentable, absent a showing of some properties significantly different from those of Milton's zeoliteR.

[5][6][7]No reason exists for applying the law relating to structural obviousness of those compounds which are homologs or isomers of each other to this case. When the PTO seeks to rely upon a chemical theory, in establishing a *prima facie* case of obviousness, it must provide evidentiary support for the existence and meaning of that theory. *In re Mills*, 47 CCPA 1185, 1191, 281 F.2d 218, 223-24, 126 USPQ 513, 517 (1960). The known structural relationship between adjacent homologs, for example, supplies a chemical theory upon which a *prima facie* case of obviousness of a compound may rest. A zeolite, like those of the instant case, is not a compound which is a homolog or isomer of another, but is a mixture of various compounds related to each other by a particular crystal structure. Moreover, no other chemical theory has been cited as a basis for considering appellants' zeolite as *prima facie* obvious in view of Milton's zeoliteR.

[8]The board's apparent rejection of appellants' argument that the prior art discloses no method for obtaining the claimed zeolite, on the ground that the claims are drawn to the composition, was incorrect. One of the assumptions underlying a *prima facie* obviousness rejection based upon a structural relationship between compounds, such as adjacent homologs, is that a method disclosed for producing one would provide those skilled in the art with a method for producing the other. That assumption does not apply, however, to the present case.

[9]Determining whether a chemical composition is *prima facie* obvious from another may rest on whether differences in structure and properties of the compositions can be accounted for by obvious modifications in the synthesis process or by obvious modifications of one composition to yield the other. If the differences in X-ray diffraction data between the zeolites here involved had indicated an actual difference in crystal structure, the present record would belie a conclusion that such differences resulted from obvious modifications of any prior art synthesis process or from obvious modifications of Milton's zeolite R to yield the claimed zeolite.⁸

[10][11][12]Though nonobviousness of appellants' process for preparing their
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claimed composition would not be determinative of nonobviousness of the composition, a holding that the composition would have been nonobvious would require that the prior art fail to disclose or render obvious a process for preparing it.

[I]f the prior art of record fails to disclose or render obvious a method for making a

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claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious * * *

In re Hoeksema, 55 CCPA 1493, 1500, 399 F.2d 269, 274, 158 USPQ 596, 601 (1968) (footnote omitted). Failure of the prior art to disclose or render obvious a method for making any composition of matter, whether a compound or a mixture of compounds like a zeolite, precludes a conclusion that the composition would have been obvious. Hence the board, having concluded that the involved zeolites were different, was incorrect in its apparent disregard of "other factors which must be given weight in determining whether the subject matter as a whole would have been obvious, namely, whether the prior art suggests the particular structure or form of the * * * composition as well as suitable methods of obtaining that structure or form." In re Cofer, 53 CCPA 830, 835, 354 F.2d 664, 668, 148 USPQ 268, 271 (1966).

Conclusion

The present record having failed to establish that the claimed zeolite is a different crystalline material from that of Milton's zeolite R, the decision of the board sustaining the rejection of claims 1 and 2 under 35 USC 103 is *affirmed*.

Affirmed.

Footnotes

Footnote 1. The subscript "n/2" should read "2/n". Appellants have filed an amendment to correct the error.

Footnote 2. For iron-containing reactant mixtures, Fe₂O₃ from about 0.5 to 2.5 weight percent, based on the weight of silica, is said to be effective. For chromium-containing reactant mixtures, 0.5. to 1.0 mole of Cr₂O₃per mole of Al₂O₃ is described as satisfactory.

Footnote 3. Examiner-in-Chief Sturtevant filed a specially concurring opinion, setting forth her view that using the data in Table B, as opposed to the more complete detailed data of Table A, to define the X-ray diffraction pattern in the claims was an insufficient method of "fingerprinting" appellants' zeolite.

Footnote 4. The present case illustrates the value, in appropriate cases, of adding a §103 rejection to a rejection under §102.

Footnote 5. Appellants' zeolite is claimed as having d-spacings

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13.4 Å and 8.5 Å of medium relative intensity. Milton's zeolite R is not disclosed as having such d-spacings. Other alleged differences in appellants' zeolite are said to be reflected by d-spacings 5.47 Å and 4.23 Å.

Footnote 6. "Polycrystalline" is defined as "1. Pertaining to a material composed of aggregates of individual crystals. 2. Characterized by variously oriented crystals." McGraw-Hill Dictionary of Scientific and Technical Terms 1146 (1974). The properties of polyerystalline materials are largely the average of the properties of the individual crystals. Where the single crystals in a composition of matter are not large enough for individual handling, the crystalline properties are identified through powder, rather than single crystal, diffraction data. The polycrystalline nature of zeolites dictates the use of powder diffraction data for distinguishing one zeolite species from another.

Footnote 7. The X-ray diffraction data for the various ion-exchanged forms of zeolite H are disclosed as follows:

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA PLUS at 1-800-452-7773 or 202-452-4323.

Footnote 8. Assuming appellants' zeolite has a different crystal structure from Milton's zeolite R, nothing of record indicates that one skilled in the art would be able to prepare the claimed zeolite by a process employing Cr₂O₃ or Fe₂O₃ or otherwise.

- End of Case -

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1300, 1302 (Bd. Pat. App. & Inter. 1993) states that obviousness cannot be established by combining references “without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done” (emphasis added), reading the quotation in context it is clear that while there must be motivation to make the claimed invention, there is no requirement that the prior art provide the same reason as the applicant to make the claimed invention.

In *In re Linter* the claimed invention was a laundry composition consisting essentially of a dispersant, cationic fabric softener, sugar, sequestering phosphate, and brightener in specified proportions. The claims were rejected over the combination of a primary reference which taught all the claim limitations except for the presence of sugar, and secondary references which taught the addition of sugar as a filler or weighting agent in compositions containing cationic fabric softeners. Appellant argued that in the claimed invention, the sugar is responsible for the compatibility of the cationic softener with the other detergent components. The court sustained the rejection, stating “The fact that appellant uses sugar for a different purpose does not alter the conclusion that its use in a prior art composition would be [sic, would have been] *prima facie* obvious from the purpose disclosed in the references.” 173 USPQ at 562.

In *In re Dillon*, applicant claimed a composition comprising a hydrocarbon fuel and a sufficient amount of a tetra-orthoester of a specified formula to reduce the particulate emissions from the combustion of the fuel. The claims were rejected as obvious over a reference which taught hydrocarbon fuel compositions containing tri-orthoesters for dewatering fuels, in combination with a reference teaching the equivalence of tri-orthoesters and tetra-orthoesters as water scavengers in hydraulic (nonhydrocarbon) fluids. The Board affirmed the rejection finding “there was a ‘reasonable expectation’ that the tri- and tetra-orthoester fuel compositions would have similar properties based on ‘close structural and chemical similarity’ between the tri- and tetra-orthoesters and the fact that both the prior art and Dillon use these compounds ‘as fuel additives’.” 919 F.2d at 692, 16 USPQ2d at 1900. The court held “it is not necessary in order to establish a *prima facie* case of obviousness . . . that there be a suggestion or expectation from *the prior art* that the

claimed [invention] will have the same or a similar utility as *one newly discovered by applicant*,” and concluded that here a *prima facie* case was established because “[t]he art provided the motivation to make the claimed compositions in the expectation that they would have similar properties.” 919 F.2d at 693, 16 USPQ2d at 1901 (emphasis in original).

See MPEP § 2145, paragraph II for case law pertaining to the presence of additional advantages or latent properties not recognized in the prior art.

2144.01 Implicit Disclosure

“[I]n considering the disclosure of a reference, it is proper to take into account not only specific teachings of the reference but also the inferences which one skilled in the art would reasonably be expected to draw therefrom.” *In re Preda*, 401 F.2d 825, 826, 159 USPQ 342, 344 (CCPA 1968) (A process for catalytically producing carbon disulfide by reacting sulfur vapor and methane in the presence of charcoal at a temperature of “about 750-830°C” was found to be met by a reference which expressly taught the same process at 700°C because the reference recognized the possibility of using temperatures greater than 750°C. The reference disclosed that catalytic processes for converting methane with sulfur vapors into carbon disulfide at temperatures greater than 750°C (albeit without charcoal) was known, and that 700°C was “much lower than had previously proved feasible.”); *In re Lamberti*, 545 F.2d 747, 750, 192 USPQ 278, 280 (CCPA 1976) (Reference disclosure of a compound where the R-S-R \neq portion has “at least one methylene group attached to the sulfur atom” implies that the other R group attached to the sulfur atom can be other than methylene and therefore suggests asymmetric dialkyl moieties.).

2144.02 Reliance on Scientific Theory

The rationale to support a rejection under 35 U.S.C. 103 may rely on logic and sound scientific principle. *In re Soli*, 317 F.2d 941, 137 USPQ 797 (CCPA 1963). However, when an examiner relies on a scientific theory, evidentiary support for the existence and meaning of that theory must be provided. *In re Grose*, 592 F.2d 1161, 201 USPQ 57 (CCPA 1979) (Court held that different crystal forms of zeolites would not have been structurally obvious one from the other because there was no chemical theory supporting such

a conclusion. The known chemical relationship between structurally similar compounds (homologs, analogs, isomers) did not support a finding of *prima facie* obviousness of claimed zeolite over the prior art because a zeolite is not a compound but a mixture of compounds related to each other by a particular crystal structure.). Although the theoretical mechanism of an invention may be explained by logic and sound scientific reasoning, this fact does not support an obviousness determination unless logic and scientific reasoning would have led one of ordinary skill in the art to make the claimed invention. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993).

2144.03 Reliance on Common Knowledge in the Art or “Well Known” Prior Art [R-1]

**>In limited circumstances, it is appropriate for an examiner to take official notice of facts not in the record or to rely on “common knowledge” in making a rejection, however such rejections should be judiciously applied.

PROCEDURE FOR RELYING ON COMMON KNOWLEDGE OR TAKING OFFICIAL NOTICE

The standard of review applied to findings of fact is the “substantial evidence” standard under the Administrative Procedure Act (APA). See *In re Gartside*, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000). See also MPEP § 1216.01. In light of recent Federal Circuit decisions as discussed below and the substantial evidence standard of review now applied to USPTO Board decisions, the following guidance is provided in order to assist the examiners in determining when it is appropriate to take official notice of facts without supporting documentary evidence or to rely on common knowledge in the art in making a rejection, and if such official notice is taken, what evidence is necessary to support the examiner’s conclusion of common knowledge in the art.

A. Determine When It Is Appropriate To Take Official Notice Without Documentary Evidence To Support The Examiner’s Conclusion

Official notice without documentary evidence to support an examiner’s conclusion is permissible only

in some circumstances. While “official notice” may be relied on, these circumstances should be rare when an application is under final rejection or action under 37 CFR 1.113. Official notice unsupported by documentary evidence should only be taken by the examiner where the facts asserted to be well-known, or to be common knowledge in the art are capable of instant and unquestionable demonstration as being well-known. As noted by the court in *In re Ahlert*, 424 F.2d 1088, 1091, 165 USPQ 418, 420 (CCPA 1970), the notice of facts beyond the record which may be taken by the examiner must be “capable of such instant and unquestionable demonstration as to defy dispute” (citing *In re Knapp Monarch Co.*, 296 F.2d 230, 132 USPQ 6 (CCPA 1961)). In *Ahlert*, the court held that the Board properly took judicial notice that “it is old to adjust intensity of a flame in accordance with the heat requirement.” See also *In re Fox*, 471 F.2d 1405, 1407, 176 USPQ 340, 341 (CCPA 1973) (the court took “judicial notice of the fact that tape recorders commonly erase tape automatically when new ‘audio information’ is recorded on a tape which already has a recording on it”). In appropriate circumstances, it might not be unreasonable to take official notice of the fact that it is desirable to make something faster, cheaper, better, or stronger without the specific support of documentary evidence. Furthermore, it might not be unreasonable for the examiner in a first Office action to take official notice of facts by asserting that certain limitations in a dependent claim are old and well known expedients in the art without the support of documentary evidence provided the facts so noticed are of notorious character and serve only to “fill in the gaps” which might exist in the evidentiary showing made by the examiner to support a particular ground of rejection. *In re Zurko*, 258 F.3d 1379, 1385, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001); *Ahlert*, 424 F.2d at 1092, 165 USPQ at 421.

It would not be appropriate for the examiner to take official notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well-known. For example, assertions of technical facts in the areas of esoteric technology or specific knowledge of the prior art must always be supported by citation to some reference work recognized as standard in the pertinent art. *In re Ahlert*, 424 F.2d at 1091, 165 USPQ at 420-21. See also *In re*

the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969) (Claim 9 was directed to a process of analyzing data generated by mass spectrographic analysis of a gas. The process comprised selecting the data to be analyzed by subjecting the data to a mathematical manipulation. The examiner made rejections under 35 U.S.C. 101 and 102. In the 35 U.S.C. 102 rejection, the examiner explained that the claim was anticipated by a mental process augmented by pencil and paper markings. The court agreed that the claim was not limited to using a machine to carry out the process since the claim did not explicitly set forth the machine. The court explained that “reading a claim in light of the specification, to thereby interpret limitations explicitly recited in the claim, is a quite different thing from ‘reading limitations of the specification into a claim,’ to thereby narrow the scope of the claim by implicitly adding disclosed limitations which have no express basis in the claim.” The court found that applicant was advocating the latter, i.e., the impermissible importation of subject matter from the specification into the claim.). See also *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997) (The court held that the PTO is not required, in the course of prosecution, to interpret claims in applications in the same manner as a court would interpret claims in an infringement suit. Rather, the “PTO applies to verbiage of the proposed claims the broadest reasonable meaning of the words in their ordinary usage as they would be understood by one of ordinary skill in the art, taking into account whatever enlightenment by way of definitions or otherwise that may be afforded by the written description contained in applicant’s specification.”).

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999) (The Board’s construction of the claim limitation “restore hair growth” as requiring the hair to be returned to its original state was held to be an ** >incorrect< interpretation of the limitation. The court held that, consistent with applicant’s disclosure and the disclosure of three patents from analogous arts using the same phrase to require only some increase in hair growth, one of ordinary skill would construe

“restore hair growth” to mean that the claimed method increases the amount of hair grown on the scalp, but does not necessarily produce a full head of hair.).

2111.01 Plain Meaning [R-2]

>

I. <THE WORDS OF A CLAIM MUST BE GIVEN THEIR “PLAIN MEANING” UNLESS THEY ARE DEFINED IN THE SPECIFICATION

While the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination. During examination, the claims must be interpreted as broadly as their terms reasonably allow. >*In re American Academy of Science Tech Center*, __ F.3d __, 2004 WL 1067528 (Fed. Cir. May 13, 2004)(The USPTO uses a different standard for construing claims than that used by district courts; during examination the USPTO must give claims their broadest reasonable interpretation).< This means that the words of the claim must be given their plain meaning unless applicant has provided a clear definition in the specification. *In re Zletz*, 893 F.2d 319, 321, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (discussed below)**>; *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372, 69 USPQ2d 1857 (Fed. Cir. 2004) (Ordinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say. Thus, “heating the resulting batter-coated dough to a temperature in the range of about 400°F to 850°F” required heating the dough, rather than the air inside an oven, to the specified temperature).< One must bear in mind that, especially in nonchemical cases, the words in a claim are generally not limited in their meaning by what is shown or disclosed in the specification. >See, e.g., *Liebel-Flarsheim Co. v. Medrad Inc.*, 358 F.3d 898, 906, 69 USPQ2d 1801, 1807 (Fed. Cir. 2004)(discussing recent cases wherein the court expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment).< It is only when the specification

provides definitions for terms appearing in the claims that the specification can be used in interpreting claim language. *In re Vogel*, 422 F.2d 438, 441, 164 USPQ 619, 622 (CCPA 1970).>See also *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870, 875, 69 USPQ2d 1865, 1868 (Fed. Cir. 2004) (“Though understanding the claim language may be aided by explanations contained in the written description, it is important not to import into a claim limitations that are not part of the claim. For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment.”); *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1369, 67 USPQ2d 1947, 1950 (Fed. Cir. 2003) (“Interpretation of descriptive statements in a patent’s written description is a difficult task, as an inherent tension exists as to whether a statement is a clear lexicographic definition or a description of a preferred embodiment. The problem is to interpret claims ‘in view of the specification’ without unnecessarily importing limitations from the specification into the claims.”); *Altiris Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371, 65 USPQ2d 1865, 1869-70 (Fed. Cir. 2003) (Although the specification discussed only a single embodiment, the court held that it was improper to read a specific order of steps into method claims where, as a matter of logic or grammar, the language of the method claims did not impose a specific order on the performance of the method steps, and the specification did not directly or implicitly require a particular order). See also paragraph III., below.< There is one exception, and that is when an element is claimed using language falling under the scope of 35 U.S.C. 112, 6th paragraph (often broadly referred to as means or step plus function language). In that case, the specification must be consulted to determine the structure, material, or acts corresponding to the function recited in the claim. *In re Donaldson*, 16 F.3d 1189, 29 USPQ2d 1845 (Fed. Cir. 1994) (see MPEP § 2181- § 2186).

In *In re Zletz, supra*, the examiner and the Board had interpreted claims reading “normally solid polypropylene” and “normally solid polypropylene having a crystalline polypropylene content” as being limited to “normally solid linear high homopolymers of propylene which have a crystalline polypropylene content.” The court ruled that limitations, not present in the claims, were improperly imported from the

specification. See also *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) (“Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their ‘broadest reasonable interpretation.’” 710 F.2d at 802, 218 USPQ at 292 (quoting *In re Okuzawa*, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)) (emphasis in original). The court looked to the specification to construe “essentially free of alkali metal” as including unavoidable levels of impurities but no more.). Compare *In re Weiss*, 989 F.2d 1202, 26 USPQ2d 1885 (Fed. Cir. 1993) (unpublished decision - cannot be cited as precedent) (The claim related to an athletic shoe with cleats that “break away at a preselected level of force” and thus prevent injury to the wearer. The examiner rejected the claims over prior art teaching athletic shoes with cleats not intended to break off and rationalized that the cleats would break away given a high enough force. The court reversed the rejection stating that when interpreting a claim term which is ambiguous, such as “a preselected level of force”, we must look to the specification for the meaning ascribed to that term by the inventor.” The specification had defined “preselected level of force” as that level of force at which the breaking away will prevent injury to the wearer during athletic exertion. It should be noted that the limitation was part of a means plus function element.)>

II. <“PLAIN MEANING” REFERS TO THE >ORDINARY AND CUSTOMARY< MEANING GIVEN TO THE TERM BY THOSE OF ORDINARY SKILL IN THE ART

**>Claim terms are presumed to have the ordinary and customary meanings attributed to them by those of ordinary skill in the art. *Sunrace Roots Enter. Co. v. SRAM Corp.*, 336 F.3d 1298, 1302, 67 USPQ2d 1438, 1441 (Fed. Cir. 2003); *Brookhill-Wilk I, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298 67 USPQ2d 1132, 1136 (Fed. Cir. 2003)(“In the absence of an express intent to impart a novel meaning to the claim terms, the words are presumed to take on the ordinary and customary meanings attributed to them by those of ordinary skill in the art.”). It is the use of the words in the context of the written description and customarily by those skilled in the relevant art that accurately

reflects both the “ordinary” and the “customary” meaning of the terms in the claims. *Ferguson Beaugard/Logic Controls v. Mega Systems*, 350 F.3d 1327, 1338, 69 USPQ2d 1001, 1009 (Fed. Cir. 2003) (Dictionary definitions were used to determine the ordinary and customary meaning of the words “normal” and “predetermine” to those skilled in the art. In construing claim terms, the general meanings gleaned from reference sources, such as dictionaries, must always be compared against the use of the terms in context, and the intrinsic record must always be consulted to identify which of the different possible dictionary meanings is most consistent with the use of the words by the inventor.); *ACTV, Inc. v. The Walt Disney Company*, 346 F.3d 1082, 1092, 68 USPQ2d 1516, 1524 (Fed. Cir. 2003) (Since there was no definition given for the term “URL” in the specification, the term should be given its broadest reasonable interpretation and take on the ordinary and customary meaning attributed to it by those of ordinary skill in the art; thus, the term “URL” was held to encompass both relative and absolute URLs.); and *E-Pass Technologies, Inc. v. 3Com Corporation*, 343 F.3d 1364, 1368, 67 USPQ2d 1947, 1949 (Fed. Cir. 2003) (Where no explicit definition for the term “electronic multi-function card” was given in the specification, this term should be given its ordinary meaning and broadest reasonable interpretation; the term should not be limited to the industry standard definition of credit card where there is no suggestion that this definition applies to the electronic multi-function card as claimed, and should not be limited to preferred embodiments in the specification.).

The ordinary and customary meaning of a term may be evidenced by a variety of sources, *Brookhill-Wilk I, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1298, 67 USPQ2d 1132, 1136 (Fed. Cir. 2003), including: the claims themselves, *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999); dictionaries and treatises, *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202, 64 USPQ2d 1812, 1818 (Fed. Cir. 2002); and the written description, the drawings, and the prosecution history, see, e.g., *DeMarini Sports, Inc. v. Worth, Inc.*, 239 F.3d 1314, 1324, 57 USPQ2d 1889, 1894 (Fed. Cir. 2001). If extrinsic reference sources, such as dictionaries, evidence more than one definition for the term, the intrinsic record must be con-

sulted to identify which of the different possible definitions is most consistent with applicant’s use of the terms. *Brookhill-Wilk I*, 334 F. 3d at 1300, 67 USPQ2d at 1137; see also *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250, 48 USPQ2d 1117, 1122 (Fed. Cir. 1998) (“Where there are several common meanings for a claim term, the patent disclosure serves to point away from the improper meanings and toward the proper meanings.”). If more than one extrinsic definition is consistent with the use of the words in the intrinsic record, the claim terms may be construed to encompass all consistent meanings. *Tex. Digital*, 308 F.3d at 1203, 64 USPQ2d at 1819. See also *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001)(explaining the court’s analytical process for determining the meaning of disputed claim terms); *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999)(“[W]ords in patent claims are given their ordinary meaning in the usage of the field of the invention, unless the text of the patent makes clear that a word was used with a special meaning.”). **>Compare *MSM Investments Co. v. Carolwood Corp.*, 259 F.3d 1335, 1339-40, 59 USPQ2d 1856, 1859-60 (Fed. Cir. 2001) (Claims directed to a method of feeding an animal a beneficial amount of methylsulfonylmethane (MSM) to enhance the animal’s diet were held anticipated by prior oral administration of MSM to human patients to relieve pain. Although the ordinary meaning of “feeding” is limited to provision of food or nourishment, the broad definition of “food” in the written description warranted finding that the claimed method encompasses the use of MSM for both nutritional and pharmacological purposes.); and *Rapoport v. Dement*, 254 F.3d 1053, 1059-60, 59 USPQ2d 1215, 1219-20 (Fed. Cir. 2001) (Both intrinsic evidence and the plain meaning of the term “method for treatment of sleep apneas” supported construction of the term as being limited to treatment of the underlying sleep apnea disorder itself, and not encompassing treatment of anxiety and other secondary symptoms related to sleep apnea.).

Furthermore, the specification must be reviewed to determine “whether the presumption of ordinary and customary meaning is rebutted.” *Tex. Digital*, 308 F.3d at 1204. “The presumption will be overcome where the patentee, acting as his own lexicographer,

has set forth a definition for the term different from its ordinary and customary meaning or where the patentee has disavowed or disclaimed scope of coverage, by using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1368, 70 USPQ2d 1209, 1214 (Fed. Cir. 2004). See also paragraph III., below.

III. <APPLICANT MAY BE OWN LEXICOGRAPHER

**>An applicant is entitled to be his or her own lexicographer and may rebut the presumption that claim terms are to be given their ordinary and customary meaning by clearly setting forth a definition of the term that is different from its ordinary and customary meaning(s). See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) (inventor may define specific terms used to describe invention, but must do so "with reasonable clarity, deliberateness, and precision" and, if done, must "set out his uncommon definition in some manner within the patent disclosure" so as to give one of ordinary skill in the art notice of the change in meaning) (quoting *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88, 21 USPQ2d 1383, 1386 (Fed. Cir. 1992)). Where an explicit definition is provided by the applicant for a term, that definition will control interpretation of the term as it is used in the claim. *Toro Co. v. White Consolidated Industries Inc.*, 199 F.3d 1295, 1301, 53 USPQ2d 1065, 1069 (Fed. Cir. 1999) (meaning of words used in a claim is not construed in a "lexicographic vacuum, but in the context of the specification and drawings"). Any< special meaning assigned to a term "must be sufficiently clear in the specification that any departure from common usage would be so understood by a person of experience in the field of the invention." *Multiform Desiccants Inc. v. Medzam Ltd.*, 133 F.3d 1473, 1477, 45 USPQ2d 1429, 1432 (Fed. Cir. 1998). See also *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999) and MPEP § 2173.05(a).

2111.02 Effect of Preamble [R-2]

The determination of whether a preamble limits a claim is made on a case-by-case basis in light of the facts in each case; there is no litmus test defining when a preamble limits the scope of a claim. *Catalina*

Mktg. Int'l v. Coolsavings.com, Inc., 289 F.3d 801, 808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). See *id.* at 808-10, 62 USPQ2d at 1784-86 for a discussion of guideposts that have emerged from various decisions exploring the preamble's effect on claim scope, as well as a hypothetical example illustrating these principles.

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165-66 (Fed. Cir. 1999). See also >*Jansen v. Rexall Sundown, Inc.*, 342 F.3d 1329, 1333, 68 USPQ2d 1154, 1158 (Fed. Cir. 2003)(In considering the effect of the preamble in a claim directed to a method of treating or preventing pernicious anemia in humans by administering a certain vitamin preparation to "a human in need thereof," the court held that the claims' recitation of a patient or a human "in need" gives life and meaning to the preamble's statement of purpose).< *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) (A preamble reciting "An abrasive article" was deemed essential to point out the invention defined by claims to an article comprising abrasive grains and a hardened binder and the process of making it. The court stated "it is only by that phrase that it can be known that the subject matter defined by the claims is comprised as an abrasive article. Every union of substances capable *inter alia* of use as abrasive grains and a binder is not an 'abrasive article.'" Therefore, the preamble served to further define the structure of the article produced.).

PREAMBLE STATEMENTS LIMITING STRUCTURE

Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (The determination of whether preamble recitations are structural